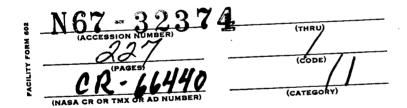
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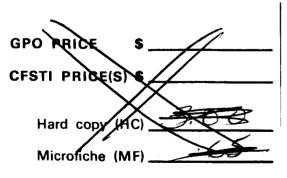
ASSEMBLY/STERILIZER FACILITY FEASIBILITY PROGRAM FINAL REPORT

VOLUME II (APPENDICES)

CONTRACT NO. NAS 1-5381



Distribution of this report is provided in the interest of information and in the author or organization that prepared it.



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RE-ENTRY SYSTEMS DEPARTMENT

THIS FINAL REPORT CONSISTS OF TWO VOLUMES:

- VOLUME NO. I -- CONTAINS SECTIONS
 I THROUGH IV
- VOLUME NO. II CONTAINS APPENDICES A THROUGH E

DOCUMENT NO. 67SD604 21 FEBRUARY 1967

ASSEMBLY/STERILIZER FACILITY FEASIBILITY PROGRAM FINAL REPORT

VOLUME II (APPENDICES)

CONTRACT NO. NAS 1-5381

PREPARED FOR

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APPENDIX A: NASA STATEMENT OF WORK

NASA STATEMENT OF WORK L-5944A FOR A RESEARCH PROGRAM TO DEMONSTRATE THE FEASIBILITY OF AN ASSEMBLY/STERILIZER FACILITY

Introduction

This contract shall consist of a study to demonstrate the feasibility of sterilizing a spacecraft using an Assembly/Sterilizer facility. The Assembly/Sterilizer is essentially an ultrabioclean room facility which allows sterilization of a disassembled spacecraft, and subsequent assembly, check-out, adjustment, and, if neccessary, repair of the spacecraft in a sterile environment. All human operators are to be topologically isolated from the spacecraft after sterilization operations have been initiated. The Contractor, in order to carry out this study, shall provide, at his expense, a pilot Assembly/Sterilizer of sufficient size and capability to represent a true analogue of the proposed full-scale facility.

Tasks

The following tasks shall be undertaken to accomplish the program objectives:

Task I - Test Sample

- 1.1 <u>Design</u> The Contractor shall design and develop a test sample to create the greatest realism in the demonstration program. The optimum component shall employ a reasonable number of spacecraft materials, electronic parts and assembly techniques, and shall be capable of a usefull performance function. The test sample shall consist of a one-stage printed circuit audio amplifier* mounted on supporting braces which are in turn attached to a section of spacecraft skin bonded to a heat-shield material. This sample shall have at <u>least six</u> (6) common types of spacecraft electronic piece parts (transistor, resistor, capacitor, thermocouple, terminal, and printed circuit board); three (3) spacecraft materials (aluminum skin and braces, ESM heat shield, and bonding); and four (4) assembly techniques (adhesive bonding, riveting, soldering, and screws). Developmental testing shall be performed to assure the compatibility of the test sample with the NASA dry-heat terminal sterilization specification (135°C for 24 hours). For the purposes of this program the test sample must survive the terminal sterilization heating requirement and operate afterwards for at least twenty (20) hours within the specified test plan requirements.
- 1.2 <u>Fabrication</u> Test sample fabrication prior to sterilization and assembly shall be performed under clean room conditions with periodic cleaning to reduce, and biological assay as required, to determine the biological load. The parts used for the test samples shall be of sufficient quality to meet the NASA terminal sterilization requirement of 135° C for twenty-four hours, and for the purpose of this study, operate after the heat cycle for at least twenty (20) hours within the specified test plan requirements. The total number of samples to be fabricated and tested shall be fifty (50).
- 1.3 Test The test samples shall be subjected to full acceptance tests to assure their uniformity of construction and adherence to original design requirements. In addition, they shall receive a complete operational check including the logging of basic input and output parameters. These parameters logged prior to, and after the sterilization period, shall be examined to determine the effects of the sterilization cycle on the operation of the test sample.
- * Changed to "binary counter" with NASA Langley Technical Representatives concurrence.

Task 2 - Manipulation Test, Sterilization Verification, and Feasibility

Demonstration

2.1 <u>Test Planning</u> - Complete detailed test plans shall be prepared by the Contractor and submitted to the National Aeronautics and Space Administration for review and approval. These plans shall consist of, but not be limited to, the following:

(a) Manipulation Tests

The manipulation tests will consist of a limited human-factor test to study the limitations and other problems imposed on the operator by the gloves and his limited access within the pilot Assembly/Sterilizer, and to provide a preliminary investigation into tools suitable for sterile assembly and sterilization facility procedures. Operators shall be required to perform a wide range of operations using hand tools of the types anticipated for use in the Full-Scale Facility. Studies shall be made of the restrictions to the manual dexterity of an operator, tool restrictions, tool cleaning problems, tool modifications required, and other limitations imposed on the operators.

(b) Sterilization Verification

The operation of the prototype Assembly/Sterilizer shall be verified by performing sterilization cycles on stainless steel strips seeded with a known biological load. The sterilization shall be performed by using both dry heat and the steam autoclave. The types of micro-organisms to be used to verify the operation of the Assembly/Sterilizer and methods of assay shall be outlined in detail in the test plan.

(c) Feasibility Demonstration

The objective of the feasibility demonstration shall be to develop proper procedures for the application of the Assembly/Sterilizer facility and to prove its practicality as a system for the support of an interplanetary spacecraft sterilization program.

The demonstration shall consist of performing typical sterilization, assembly, checkout, and packaging operations on the test samples. One of the primary ground rules will be to perform in the Assembly/Sterilizer only those operations which are representative of operations in a full-scale facility.

Task 3 - Bioassay

The sterilization verification and feasibility demonstration tests will require seeding of selected samples, bioload assay before sterilization, and bioassay of sterilized samples. The samples shall be assayed in several different configurations to gain statistical knowledge in the use of various methods. For example, the sample may be assayed as a unit in the Assembly/Sterilizer or it may be disassembled and assayed as piece parts. The Contractor shall provide the bioassay facilities and personnel required to support this study program.

NAS1-5381 Exhibit A

Task 4 - Full-Scale Facility Design Study

The Contractor shall prepare a preliminary design for a full-scale Assembly/ Sterilizer. This shall include preliminary specifications, plan views, block diagrams, support criteria description, and cost estimates.

APPENDIX B: TEST PLAN

The Test Plan which is presented in its entirety in this Appendix was published and distributed as Document No. 65SD981, Revision A dated 20 January 1966 and is entitled, "Test Plan for A Program to Demonstrate the Feasibility of an Assembly/Sterilizer Facility."

I. INTRODUCTION

This test plan describes a program to provide the initial demonstration of the technical feasibility of a facility which permits the decontamination and sterilization of spacecraft with capability for subsequent checkout, adjustment, repair, and encapsulation in a biological barrier under sterile conditions. This is demonstrated using a reduced scale analogue of the Assembly/Sterilizer Facility. The test program is composed of three major types of tests:

- Sterilization Verification
- Manipulation Tests
- Feasibility Demonstration

These tests are described in detail herein. They may be summarized as follows:

The sterilization verification tests assure that the A/S Analogue chambers are achieving the required decontamination and sterilization using the prescribed treatments. These tests consist of two complete cycles of operation of the A/S Analogue subjecting a total of 150 specially prepared specimens to the treatments of ETO/Freon decontamination, dry heat sterilization and wet heat sterilization. The specimens are stainless steel strips with known, high resident populations of viable micro-organisms.

The manipulation tests consist of a limited human factor test to determine the limitations imposed on a worker performing assigned tasks in the A/S Analogue, and problems resulting from this work environment. In addition, tools suitable for sterile assembly and sterilization facility procedures will be investigated.

The feasibility demonstration consists of the performance of five cycles of A/S Analogue operation including decontamination, and sterilization, and sterile checkout, repair, assembly, packaging and recycle repair of a special component simulating typical spacecraft hardware. A total of 50 of these components are available for this program. However, the present plan calls for holding 5 of these for use by NASA Langley. In addition, 131 biologically seeded stainless steel strips will also be processed during these cycles to broaden the biological base of the demonstration.

Successful completion of this test program will demonstrate that the Assembly/Sterilizer system design concept can be successfully implemented in a reduced
scale analogue and that this analogue facility can satisfy all applicable biological and physical requirements.

II. STERILIZATION VERIFICATION

A. OBJECTIVE

The objective of the sterilization verification is to demonstrate that the A/S Analogue is satisfactorily performing the prescribed decontamination and sterilization treatments. This provides a base line condition from which to measure results of the feasibility demonstrations. The operation shall be verified by performing the decontamination and sterilization treatments on stainless steel strips with a known biological load and performing biological assay on the strips after the treatments.

B. TEST EQUIPMENT AND FACILITIES

1. STERILITY CONTROL SPECIMENS

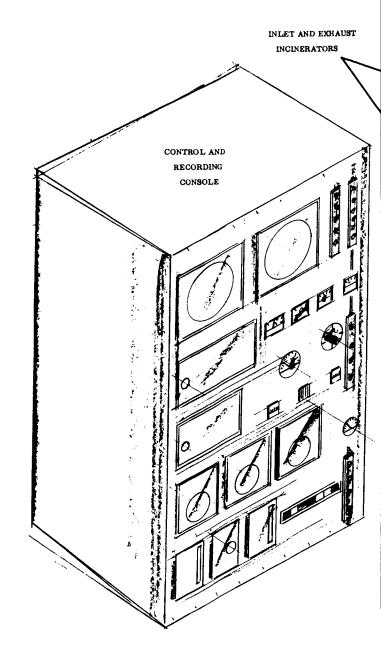
The Sterility Control Specimens (S/C Specimens) will be stainless steel strips measuring 1" x 2" x 0.06". Iron-constantan thermocouple junctions will be spot-welded to the undersurface of approximately one-half of the specimens. All specimens will be inoculated with an aqueous suspension of spores of either \underline{B} . subtilis var. niger or \underline{B} . stearothermophilus to produce strips with resident populations of 1 x 10^6 , 1 x 10^8 , and 1 x 10^{10} spores. These specimens will be prepared and assayed in accordance with procedures presented in Appendix A.

2. ASSEMBLY/STERILIZER ANALOGUE

The A/S Analogue consists of a main chamber and two pass-throughs. Decontamination by ETO/Freon and primary sterilization by dry heat are performed in the main chamber which then maintains a sterile, laminar flow, dry nitrogen environment for assembly, checkout, and canning of parts, components, or assemblies. Human operators using gloves protruding through the sides of the chamber will be able to perform assigned tasks in the main chamber after sterilization without jeopardizing the sterility of the chamber and its contents. One of the pass-throughs is capable of ETO/Freon decontamination and dry heat sterilization. The second pass-through is a steam autoclave. A visualization of the A/S Analogue is shown in Figure 2-1. Details of the A/S Analogue are described in Section IIB of the First Quarterly Progress Report, Document No. 65SD982.

a. Construction

The main chamber and both pass-throughs will be made of welded stainless steel with necessary doors, an observation window, gloves, and an electrical junction box. All openings into the A/S Analogue and between the main chamber and pass-throughs will be gasketed with materials capable of providing a positive seal and withstanding repeated exposure to the sterilization environment without degradation. The observation window will be a similarly gasketed, heat-resistant, glass plate.



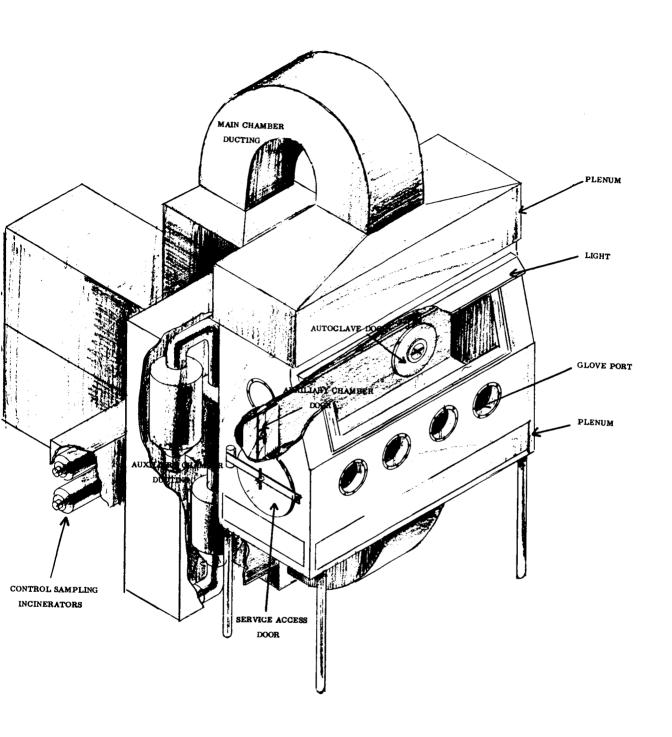


Figure 2-1 Assembly/Sterilizer Analog

The size of the main chamber and pass-throughs, and the window and glove locations have been chosen to permit convenient operations on components and small assemblies. The main chamber must provide space for sterilization, assembly, and checkout of the components as well as space for operator hand movements, tools, and sterilizable containers.

b. Environment Control

A block diagram of the environment control system is shown in Figure 2-2. The working atmosphere in the main chamber will be sterile, laminar flow, dry nitrogen at a positive pressure relative to the adjoining areas. The nitrogen will be admitted from a plenum chamber at the top of the chamber through a filter bank and removed through a grated chamber bottom, thereby establishing a vertical laminar flow pattern over the entire main chamber and its contents. The nitrogen will circulate in closed-loop, pass through dry impingment filters which will remove 99.99 percent of particles in the 0.3 to 0.5 micron range and will be temperature-controlled before the admission to the chamber.

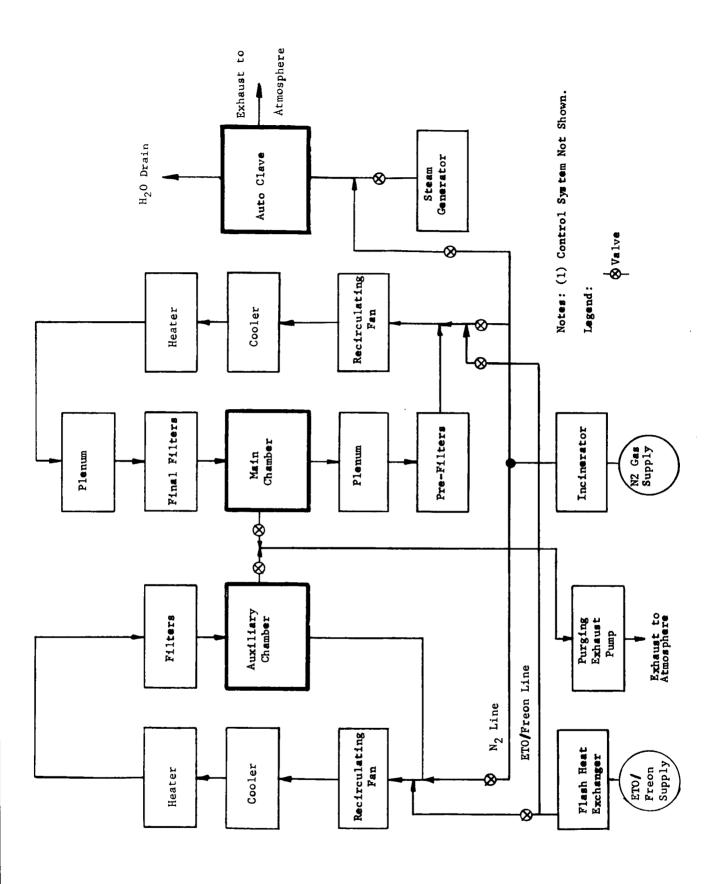
The dry heat pass-through will have a similarly controlled atmosphere except that there will be no provision for laminar flow of the gas. Since the A/S Analogue will be operated in a laminar flow room and there will be no operations in the pass-through, laminar flow in this chamber is not felt economically justified as part of the analogue of the Full-Scale facility. Once the main chamber and its contents have been sterilized, the pass-through will be kept at a pressure negative with respect to the main chamber but positive with respect to the outside. The autoclave will expose its contents to steam at approximately one atmosphere gage pressure. After the steam, the autoclave will be purged and filled with dry sterile nitrogen. Opening of the pass-throughs to the outside or of the inner doors of the pass-throughs to the main chamber will cause a loss of gas. Sterile dry make-up gas will be added to maintain a positive pressure by introducing the gas through an incinerator.

c. Operator Access

Prior to sterilization, technicians in clean-room clothing can reach into the main chamber through the pass-throughs on the side access doors to place equipment, do maintenance, or perform janitorial services. After sterilization operators will have access to the inside of the sterilized A/S only through the gloves.

d. Control Console

The A/S Analogue will employ a control console to provide control and monitoring of the sterile environment. The chamber environments, laminar air-flow equipment, sterilization heating equipment, cooling equipment, gas supply, and autoclave auxiliary equipment (steam generator) will be controlled from the control station.



e. Electrical Checkout Equipment

Electrical equipment for component checkout is located outside the A/S Analogue. All connections to this equipment will be made through a sterilizable patch panel on the back of the main chamber. Sterilizable test cables will provide connections between the component and the patch panel. The patch panel design will permit electrical signal and power transmission while maintaining a positive barrier against leakage of gas or microorganisms.

C. TEST PLAN

The tests for the sterilization verification will consist of three performances of a sterilization verification cycle. In this cycle S/C specimens seeded with known organisms will be subjected to ETO decontamination and dry heat sterilization in the main and auxiliary chambers and steam sterilization in the autoclave. After each of these treatments, bio-assays will be performed on the samples to determine the efficacy of the treatment.

The test cycle that will be employed in the verification is shown in detail in Table 2.1 and Figure 2-3. This cycle will be repeated 3 times with 50 S/C specimens being employed for each cycle. These specimens will be assayed in accordance with Appendix A.

The sterilization and decontamination treatments that will be employed in these cycles are:

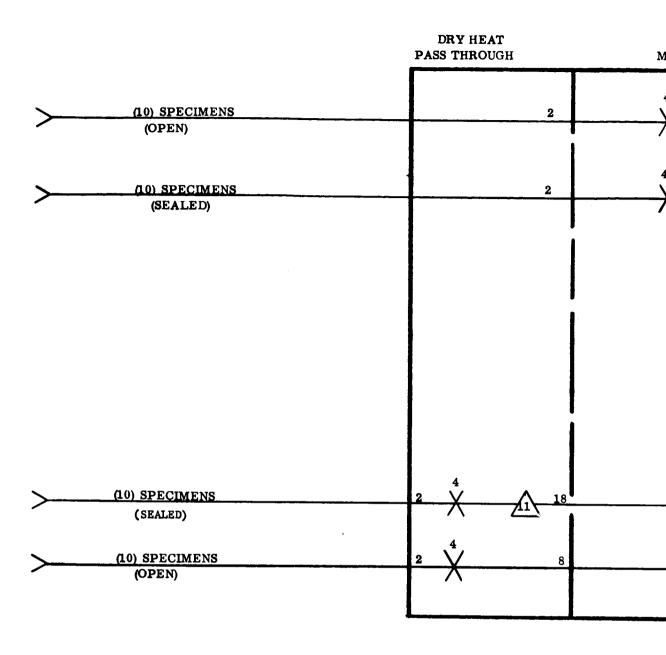
Dry Heat Sterilization:
Wet Heat Sterilization:
ETO/Freon Decontamination:

+135°C for 24 hours +121°C for 30 minutes 12% ETO/88% Freon-12, 50-60% relative humidity, at +130°F for 2 hours, with a gas concentration of 400 mg/liter nominal.

A typical operating plan, enclosed as Appendix D, describes facility operation to perform the steps of the verification cycle.

TABLE 2.1 - STERILIZATION VERIFICATION CYCLE STERILIZATION CONTROL SPECIMENS

Step	Time hr.	Description	Duration hr.
1.	0	Prepare A/S Analogue	4
2.	4	Place specimens in main chamber and pass-through	1/2
3.	4.5	Close up and leak check	1
4.	5.5	Decontaminate (ETO) main chamber and pass-through	6 .
5.	8.5	Prepare bio-assay materials	2
6.	10.5	Sterilize bio-assy material in autoclave	1
7.	11.5	Assay open specimens in main chamber	1
8.	12.5	Transfer open specimens from pass-through to main chamber	13
9.	13.0	Assay open specimens in main chamber	1
10.	14.0	Remove assay materials and assayed specimens through autoclave	1 2
11.	14.5	Sterilize main chamber and pass-through	40
12.	51.0	Prepare bio-assay materials	2
13.	53.0	Place specimens and bio-assay materials in autoclave	1/2
14.	53.5	Sterilize autoclave contents	1
15.	54.5	Transfer specimens and bio-assay materials from autoclave to main chamber	1 2
16.	55.0	Assay autoclaved specimens	1
17.	56.0	Assay specimens from main chamber	1
18.	57.0	Transfer specimens from pass-through to main chamber	1/2
19.	57.5	Assay specimens from pass-through	1
20.	58.5	Shut down A/S Analogue and remove specimens and assay materials from main chamber through autoclave	1/2
21.	59.0	End	



DECONTAMINATE

STERILIZE

DIOASSAY

NOTE: Numbers in parenthesies are hardware quantities; other numbers are step numbers.

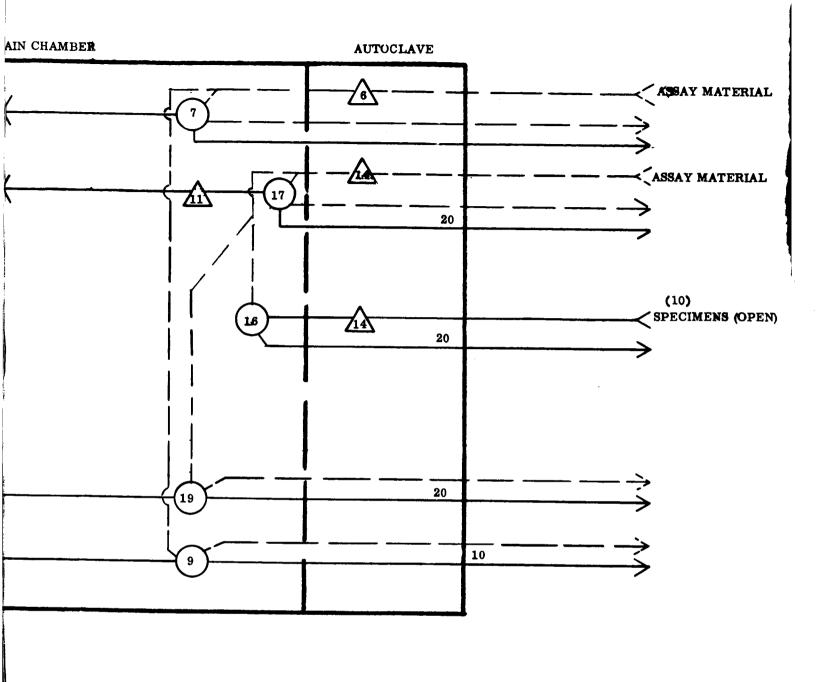


Figure 2-3 Sterilization Verification Cycle

III. MANIPULATION TESTS

A. OBJECTIVES

The objective of the Manipulation Test is to perform a limited human-factor test to study the limitations and other problems imposed on the operator by the gloves and his limited access within the Assembly/Sterilizer Analogue, and to provide a preliminary investigation into tools suitable for sterile assembly and sterilization facility procedures.

B. TEST EQUIPMENT AND FACILITY

1. TOOLS

The tools used will be manually-operated tools.

Simple hand tools employed will include, but not be limited to, the following:

- a. Screw Drivers
- b. Wrenches
 - . open-end type, straight & "S"
 - . adjustable

c. Pliers

- . slim and needle-nose types
- . slip-joint or parallel-jaw types
- . cutters
- d. Tweezers and Tongs
- e. Hand Riveting Tools
- f. Wire Strippers
- g. Connector Pin Crimp Tools

2. TEST FACILITY

The test facility will consist of the A/S analogue described in Section II B.

C. TEST PLAN

Operators will be required to perform a wide range of operations using hand tools of the types anticipated for use in the Full-Scale Facility. Pre-cleaned tools and equipment for the manipulation tests will be introduced to the main chamber through the pass-throughs. Cleaning will be required to reduce contamination of the facility; however, with an established physical configuration of the Pilot Model, sterility of the chamber interior will not affect the complexity of the manipulation problems. Therefore, it will not be necessary to fabricate special sterilizable tools or test fixtures for this test. The only limitation on the types of operations that can be investigated will be size of tools or equipment that will fit through the pass-throughs.

These tools will be used over a range of assembly conditions. Screwdrivers of varying sizes will be used to drive standard screws of a progression of sizes into tapped holes in selected Assembly devices. Some hole locations will be readily accessible; others will be more difficult to reach. Some screws will be fastened by nuts in which case holding nut and/or final tightening will be accomplished by means of a wrench. Under the more inaccessible conditions, the nuts will have to be placed to the screw using slim-nose pliers or tweezers. In other instances, off-set drivers and/or pliers will be required. Hand or "pop" riveting will be performed on a variety of experimental assembly devices over a range of positions and locations.

Experimental operators will be selected to represent normally skilled and trained personnel. They will be subjected to a period of orientation and training to assure consistent, proficient performance. Their preparation will include a candid appraisal of the various factors expected to be encountered in the pursuit of the studies. A significant part of this preparation will include familiarization with the basic function of the Assembly/Sterilizer Analogue to be used and its relationship to the full-scale facility planned for the future.

D. TOOL INVESTIGATION

A secondary aspect of the manipulation test will be an examination of tools which are amenable to use in a sterile chamber. Conventional hand tools will be identified as being suitable or not suitable. Where a tool is not suitable, but where that tool's function is considered necessary, recommendations will be made for redesign of the tool to make it suitable. This will include both the human factors and the sterilization aspects of suitability. As an example of the first, a tool may require enlargement of finger holes to accommodate the gloved hand. As an example of the second, tools such as pliers should probably be capable of disassembly to facilitate cleaning and sterilization. In addition to conventional hand tools, medical instruments will be investigated for their adapability to Assembly/Sterilizer procedures. Such instruments have the inherent advantage that, if properly designed, ease of sterilization should be a significant design parameter.

IV. FEASIBILITY DEMONSTRATION

A. OBJECTIVE

The objective of the feasibility demonstration shall be to develop proper procedures for the application of the Assembly/Sterilizer facility and to prove its practicality as a system for support of an interplanetary spacecraft sterilization program.

The demonstration shall consist of performing typical sterilization, assembly, checkout, and packaging operations on the test samples. One of the primary ground rules will be to perform in the Assembly/Sterilizer only those operations which are representative of operations in a full-scale facility.

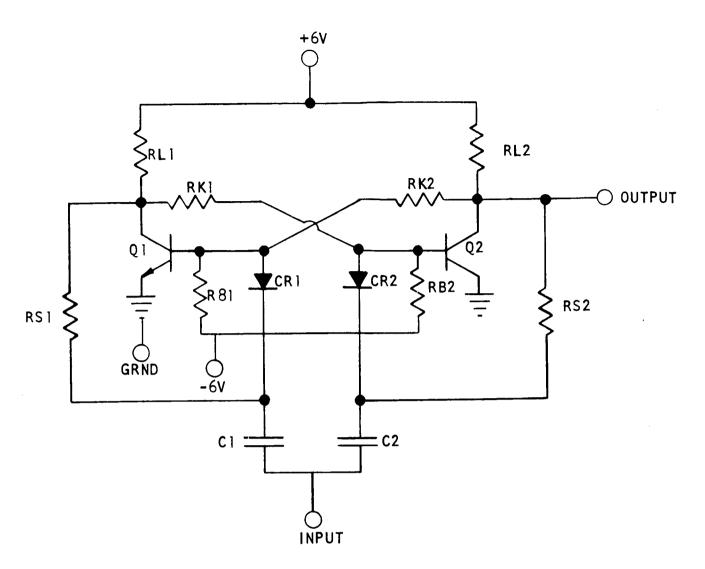
B. TEST EQUIPMENT AND FACILITY

1. TEST SAMPLE

In order to create the greatest realism in the feasibility demonstration and most accurate analogue of Full-Scale Assembly/Sterilizer operations, the use of actual spacecraft hardware would be desirable. However, the high unit cost and the number of components required for a meaningful demonstration would result in excessive test hardware costs. Furthermore, since qualified dry heat sterilizable components are not in the present inventory of spacecraft hardware, the design and qualification of components would represent prohibitive and unjustified expenditure of time and funding.

A second approach would be to sterilize and assemble groups of "parts" of simple geometric shapes made of stainless steel. Using this sterile "tinkertoy" approach would permit a simplified biological sampling situation; and if conic forms were used, the test specimens could be a good visual analogue of a spacecraft. However, the resulting specimens would not be any more than visually analogous to any realistic spacecraft equipment, and would have no useful performance capability.

A compromise has been made between the use of qualified spacecraft equipment and the "tinkertoy" blocks. By designing a simplified test sample component it is possible to achieve most of the benefit of either of the above without being restricted by high cost on the one hand or lack of realism on the other. The optimum component should employ a reasonable range of spacecraft materials, electronic parts, and assembly techniques, and should be capable of a useful performance function. The test sample selected is a printed circuit binary counter stage mounted on supporting brackets which are in turn attached to an element of spacecraft skin bonded to heat shield material. A schematic and assembly drawing of the test sample are shown in Figures 4-1 and 4-2 respectively.



```
RL1,RL2 -- 1K, ± 5% RC07
RK1,RK2 -- 3.9K, ±5% RC07
RB1, RB2-- 100K, ±5% RC07
RS1, RS2-- 10K, ±5% RC07
C1, C2 -- 470 pF, CK05CW471K
Q1, Q2 -- 2N706
CR1,CR2 -- 1N914
5 Terminals R2574P2
```

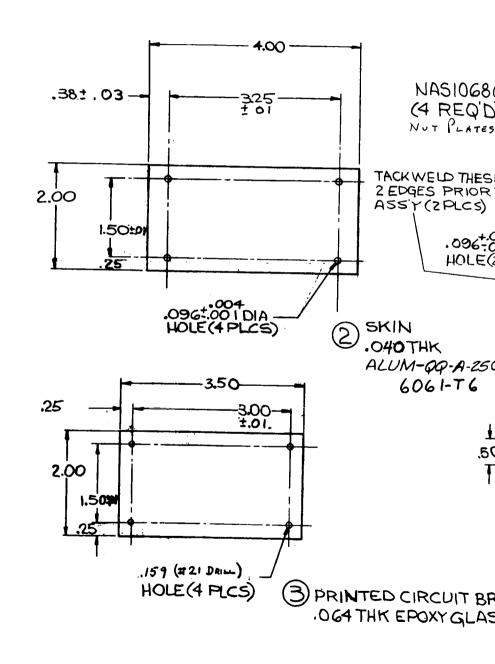
Figure 4-1 Test Sample Schematic

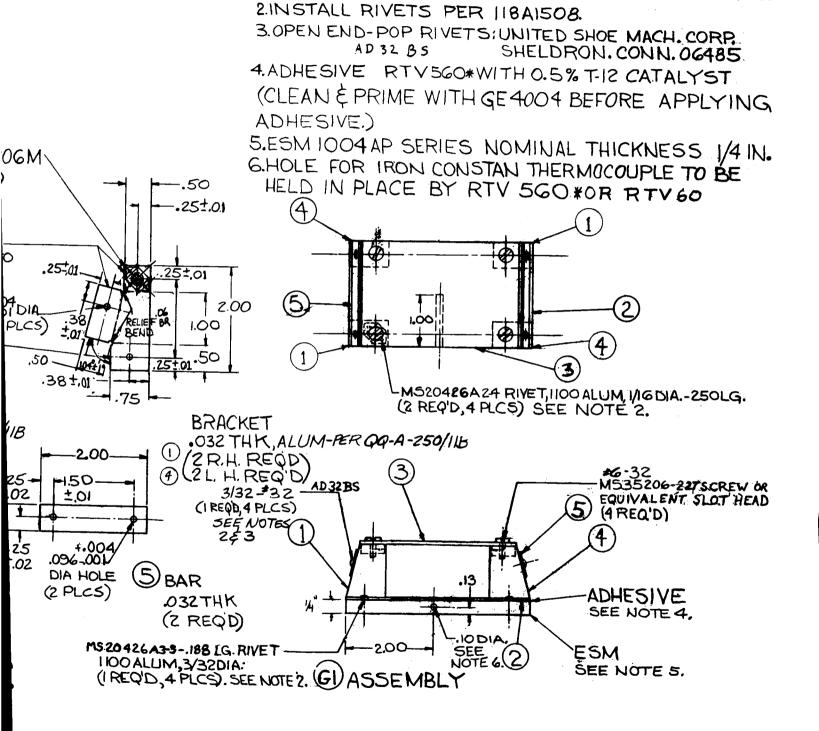
TEST SAMPLE FOR ASSEMBLY/STERILIZ

SK-56117-802

GENERAL ELECTRIC CO. RE-ENTRY SYSTEMS DEPT.

20 Dec 1965 Johnwoon





I. ALL TOLERANCES +. 03 UNLESS OTHERWISE SPECIFIED

NOTES:

Figure 4-2 Test Sample Assembly Drawing

The test sample has seven common types of spacecraft electronic piece parts (transistor, diode, resistor, capacitor, thermocouple, terminal, and printed circuit board); three typical spacecraft materials (aluminum skin and braces, ESM heat shield, and RTV bonding); and employs four assembly techniques (adhesive bonding, riveting, soldering, and screws). A breadboard of the test sample has been subjected to ultrasonic cleaning and dry heat sterilization (135° for 24 hours) followed by a 20-hour life test. No observable performance changes occurred during this test sequence.

Parts will be procured or fabricated for 50 complete test samples, plus electronic parts for an additional 15 test samples, and mechanical parts for an additional 10. The program utilization of these test samples is shown in Table 4.1.

TABLE 4.1 TEST SAMPLE UTILIZATION

		QUANTI TY			
	PURPOSE	Electrical Parts	Mechanical Par t s		
1.	 In-process bio-assay during manufacture: Procured or fabri-cated parts Semi-assembled test samples ready for A/S 	5 5	0 5		
2.	Hold for NASA Langley (Unprocessed)	5	5		
3.	Stock for demonstration cycles	<u>45</u>	<u>45</u>		
	TOTAL	6 0	55		

The utilization of the 45 test samples held as stock for demonstration cycles is described in subsequent paragraphs and is shown in Table 4.7 and Figure 4-11.

2. STERILITY CONTROL SPECIMENS

The sterility control specimens to be employed in the feasibility demonstration are only referenced here since they are described in Section II B.

3. TEST FACILITY

The test facility employed in the feasibility demonstration will be the Assembly/Sterilizer analogue referenced here and described in Section II B.

4. TEST EQUIPMENT

The test equipment required for the feasibility demonstration shall consist of the following:

- Tektronics Dual Beam Oscilloscope with C-A Dual-Trace DC Plug-in Unit
- EPIIT counter
- Peak reading voltmeter
- Test Sample Test Set (TSTS)

All of the above equipment items are standard electronic laboratory equipment except for the Test Sample Test Set (TSTS).

The test sample test set is a small chassis containing a test signal generator; a test sample output indicator; and power sources for the test sample, signal generator and indicator.

The signal generator is a free-running multivibrator whose output is a pulse train of approximately sawtooth waveform. The pulse rate is 4 pps (nom.) and the pulse amplitude is 4.8 volts (nom.). The signal generator schematic is shown in Figure 4-3.

The test sample output indicator is a one-shot triggered multivibrator flashing light indicator. This indicator produces one flash for every cycle of square wave input from the test sample. The indicator schematic is shown in Figure 4-4.

The power sources consist of two six-volt batteries which provide power for the test sample, signal generator, and indicator; and a 20-volt battery which provides power for the indicator.

5. TOOLS

The tools to be used in the Assembly/Sterilizer for the demonstration will consist of the following:

- Screwdrivers
- "POP RIVETOOL" (United Shoe Machinery Corporation, Fastener Division, Shelton, Connecticut)
- . Diagonal cutting pliers
- Heavy duty shears
- · Forceps
- · Screen parts tray
- · Test leads

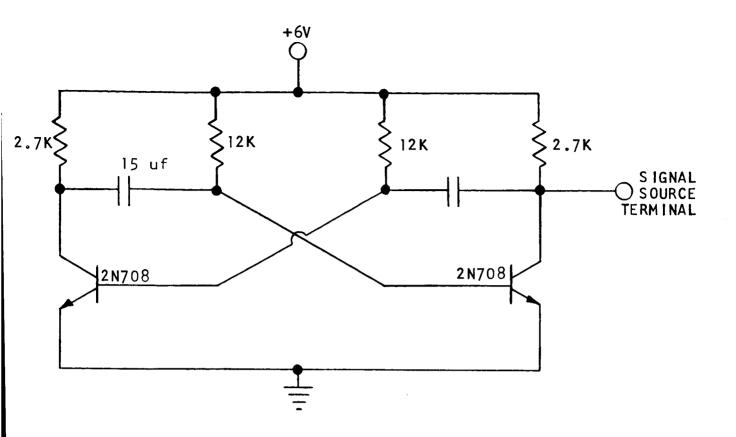


Figure 4-3 Signal Generator

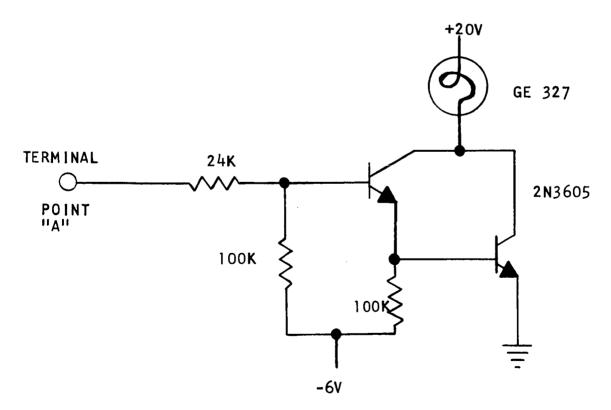


Figure 4-4 Output Indicator Schematic

The screwdrivers and "POP RIVETOOL" will be used in assembling the test samples. The test leads will be used for connecting the test leads to the electrical junction panels in the A/S, and in interconnecting test samples, for test sample checkout and for the performance of the required 20-hour life test. The screen parts tray is a small tray with a screen, or perforated metal bottom for parts handling.

A pair of forceps will also be used for parts handling.

The diagonal pliers and heavy duty shears will be used to reduce the test samples to small enough parts and fragments to permit complete immersion for sterility tests at the end of each operation cycle.

6. CONTAINERS

Containers will be used in the test program for the following three purposes:

- Containment of selected S/C specimens and isolation of them from ETO in operation cycles to assess the effects of dry heat only on the specimen microbial population.
- Sterile containment of test samples for recycle repair (in this use the container simulates the bio-barrier on a spacecraft) to permit removal of the sample from the test chamber and subsequent re-introduction to the chamber through the autoclave without exposing the sample to ambient contamination levels outside the A/S analogue or to the wet heat in the autoclave.
- Containment of S/C specimens and isolation of them from wet heat in the autoclave when processed as controls along with recycled test samples.

The containers to be used are Hazel-Atlas wide-mouth glass containers with rubber sealing metal tops (Hazel-Atlas Glass Division of Continental Can Company, Wheeling, West Virginia). Two sizes will be used: No. 817, 16 oz. and No. 818, 32 oz.

The No. 817 jar has been tested to assure its compatibility with program requirements. Lids and containers were autoclaved at 18 psig. Using new lids or previously autoclaved lids on jars, no leakage of steam into sealed jars was detected using "DRI-RITE" (anhydrous CaSO4) in the jars as a moisture indicator. The No. 818 is the same design as the No. 817 except for length, thus the tests on the No. 817 are considered applicable to the No. 818 also.

C. TEST PLAN

The tests will consist of five operation cycles including sterilization, assembly, electrical checkout, repair and packaging of the test samples.

Tasks which would produce quantities of particulate matter contamination or would create or require conditions conducive to the support of viable micro-organisms will be performed outside the Assembly/Sterilizer, where possible, on a spacecraft program and in this test program. Soldering, gas and arc welding, and brazing are representative of such operations.

The distinguishing features of each of the five demonstration cycles are summarized in Table 4.2. The quantities of test samples for the cycles range from 8 to 14 and are selected to permit achievement of the objectives of each cycle and permit the destructive bio-assay of eight test samples at the end of each cycle. There are fundamentally three different types of cycles employed; a "Normal" cycle, a repair cycle, and a recycle repair cycle.

In the normal cycle (Cycle No. 1, 3 and 5) it is assumed that there are no equipment malfunctions detected in the hardware being processed.

In the repair cycle (Cycle No. 2), it will be assumed that all of the test samples in the main chamber have indicated malfunction in the post-sterilization checkout. A simulated repair will be effected by introducing an equal quantity of test samples through the auxiliary chamber. The electronics from the replacement units will be substituted for electronics on the "failed" units, and vice versa. Since engineering tests on the test sample have given no reason to expect any actual failures in the demonstration, all "failures" will be known a priori. This will permit a significant quantity of repairs to be made and it will also permit simultaneous processing of "prime" units in the main chamber and "repair" units in the auxiliary chamber to minimize overall demonstration cycle duration.

The recycle repair cycle (Cycle No. 4) is similar to the repair cycle except that it involves the introduction of a sterile test sample in a container into the sterile main chamber for repair thus simulating repair of an on-pad failure of a sterile spacecraft. Because of the small physical size of the test sample and its container, with the consequent nominal thermal lag, the autoclave is used to pass the sterile test samples into the main chamber. This permits much more rapid surface sterilization of the test sample container, which in turn greatly reduces the probability that any possible viable organisms on the recycled test sample would be sterilized. In fact, to insure that such would not occur, S/C Specimens in similar containers will be processed through the autoclave simultaneously to verify that only container surface sterilization from their containers and a simulated repair will be effected as described above for the repair cycle.

Electrical checkouts of the test samples to be performed in the demonstration are of two kinds: a performance test and an operation verification. The equipment set-up for each of these checkouts is shown in Figures 4-5 and 4-6, respectively. In the performance test, the input and output signals for each test sample will be measured and data will be recorded. In the performance verification, the test is go/no-go with the result that a properly excited unit either does or does not cause flashing of the indicator lamp on the test sample test set. This go/no-go test may be performed with all units in the chamber

TABLE 4.2 - SUMMARY OF FEASIBILITY DEMONSTRATION TEST CYCLES

COMMENTS		Use autoclave for bio-assay material sterilization (wet load). ETO decontamination and dry heat sterilization in main chamber.	Use autoclave for blo-assay material sterilization (wet load). ETO decontamination and dry heat sterilization of 4 test samples in main chamber and 4 test samples in dry-heat pass-through. Printed circuit boards introduced through pass-through are used on bases sterilized in main chamber and vice versa.	This cycle differs from cycle No. 1 in that 5 of the test samples are placed in sterile containers after the 20 hour life test.	Sterilize main chamber before introducing test samples. Pass 5 samples through dry heat pass-through; and 5 through autoclave, surface sterilizing containers. Printed circuit boards introduced through pass-through are used on bases introduced through autoclave and vice versa.	This cycle is an exact duplicate of Cycle No. 1.
NO.	(.ян) иогтаяиа	24	24 24	24	24	24
STERILIZATION TREATMENT	NOITARUIO O DURATION	135/275	135/275 135/275	135/275	135/275 121/250	135/275
s	TYPE OF HEAT	Dry	Dry Dry	Dry	Dry Wet	Dry
TON	(.AH) NOITA RUG	2	2.2	7	2	2
DECONTAMINATION TREATMENT	S TEMPERATURE	54/130	54/130	54/130	54/130	54/130
DEC	ИЕDIЛИ	ETO	ETO ETO	ET0	ETO	ETO
	CONTROL SPECIME	27	4 4	42	5 5	27
IS	SAMPLES QUANTITY OF TES	6	44	14	N N	6
TOTAL CYCLE DURATION (HR.)		80.5	81.0	84.5	84.5	80.5
DEMONSTRATION CYCLE		"Normal" Cycle	Repair Cycle	"Normal" Cycle	Re-cycle Repair	"Normal" Cycle
CACLE NUMBER		-	2	၈	4	5
	1	!	ı		ı	ı

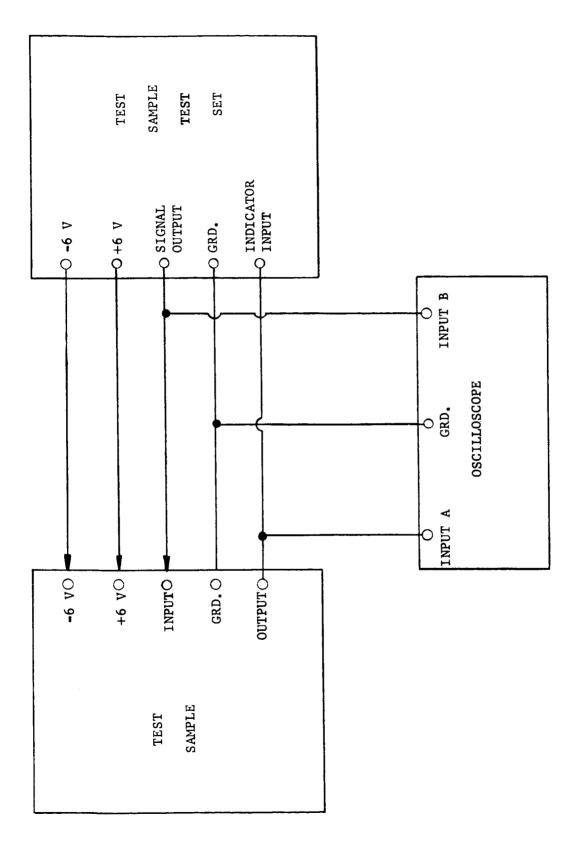


Figure 4-5 Test Sample Performance Block Diagram

Figure 4-6 Test Sample Verification Checkout

connected in cascade which will provide successive binary count-downs of the signal generator output signal. In the A/S Analogue, the performance test will be performed after sterilization and as the last step in the 20 hour life test. The verification will be performed after introduction of the test samples into the main chamber and after assembly.

The 20 hour life test will be performed with the test samples connected in cascade and with an EPUT counter measuring the duration of the cycle of the fianl unit. This is a highly sensitive test. The smallest number of test samples in cascade would be five (in Cycle No. 4) giving a countdown of 2^5 . A single skip of any one of five cascaded units would make a large and easily detected change in the duration count.

All bio-assay in the feasibility demonstration will be performed in accordance with Appendix A. It should be noted that the repeated introduction of material into the sterile main chamber for bio-assay represents a severe test of the ability of the A/S Analogue to maintain bio-integrity and simulates the biological effects of a large amount of repair activity in the full scale facility.

The salient features of the five demonstration cycles are described briefly below. The cycles will be performed in the sequence of the cycle numbers given.

DEMONSTRATION CYCLE NO. 1

The major steps of this cycle are listed in Table 4.3 and illustrated in Figure 4-7. This is a "Normal cycle" which means that all decontamination and sterilization are performed in the main chamber and there is no repair activity. The auxiliary chamber will be used only as an air lock pass-through and the autoclave is used only for sterilization of bio-assay materials.

DEMONSTRATION CYCLE NO. 2

The major steps of this cycle are listed in Table 4.4 and illustrated in Figure 4-8. This is a repair cycle in which the repair will be effected as described above, using the auxiliary chamber for processing "repair" units. The autoclave is used only for bio-assay.

DEMONSTRATION CYCLE NO. 3

The major steps of this cycle are listed in Table 4.5 and illustrated in Figure 4-9. This is a "Normal" cycle and is the same as Cycle No. 1 except that five of the test samples are placed in sterile containers for removal, to be subsequently used in the recycle repair cycle. These sterile containers are introduced to the main chamber through the autoclave.

DEMONSTRATION CYCLE NO. 4

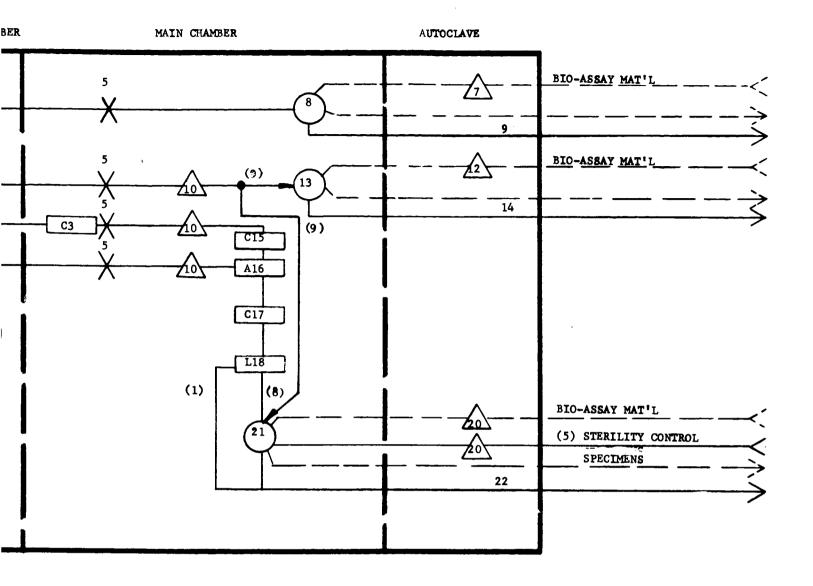
The major steps of this cycle are listed in Table 4.6 and illustrated in Figure 4-10. This is a recycle repair cycle. The test samples being recycled

TABLE 4.3 DEMONSTRATION CYCLE NO. 1 & 5

STEP	TIME (HR)	STEP DESCRIPTION	DURATION (HR)
1	0	Prepare A/S Analogue	4
1 2	4	Place 9 Test Samples, 27 S/C Specimens, and Tools	1/2
4	7	in Main Chamber	
3	4.5	Check Test Samples in Main Chamber	½ 1
4	5.0	Close-up and Leak Check in Main Chamber	1
5	6.0	Decontaminate (ETO) Main Chamber	6
6	9.0	Prepare Bio-Assay Mat'1	2
7	11.0	Sterilize Bio-Assay Mat'l in Autoclave	1
8	12.0	Assay 9 S/C Specimens	12
9	12.5	Remove Assay Mat'l and S/C Specimens through Autoclave	1 2 40 2
10	13.0	Sterilize Main Chamber (Dry Heat)	40
11	50.0	Prepare Bio-Assay Mat'1	
12	52.0	Sterilize Bio-Assay Mat'l in Autoclave	1 ½ ½ 1
13	53.0	Assay 9 S/C Specimens	1/2
14	53.5	Remove Assay mat'l and S/C Specimens through Autoclave	1 2
15	54.0	Check Test Samples	1
16	55.0	Assemble Test Samples	1 ½
17	56.0	Check Test Samples	<u>1</u> 2
18	56.5		21
19	74.5	Prepare Bio-Assy Mat'1	2
20	76.6	Sterilize Bio-Assay Mat'l and 5 S/C specimens in	1
		Autoclave	
21	77.5	Assay Main Chamber contents (except 1 Test Sample)	2
22	79.5	Remove Main Chamber contents through Autoclave	1/2
23	80.0	END	

CRITICAL PATH 1,2,3,4,5,8,9,10,13,14,15,16,17,18,21,22,23

> (9) S'	TERILITY CONTROL SPECIMENS		2
$>$ $\frac{(18)}{}$	CANNED STERILITY CONTROL SPECIMEN	18	2
> PART	S FOR (9) TEST SAMPLES		2
T001	· g		2
		· · · · · · · · · · · · · · · · · · ·	2
			:
X	DECONTAMINATE (ETO)		
•			
\triangle	STERILIZE		
	BIO-ASSAY		
\bigcup			
	CHECK TEST SAMPLES		
	NOTE	: NUMBERS IN PA	TITIES: OTHER
	ASSEMBLE TEST SAMPLES	NUMBERS ARE	STEP NUMBERS
A			
	20 Hours Tree meem		
L	20 HOUR LIFE TEST		



DEMONSTRATION CYCLE #1
AND
DEMONSTRATION CYCLE #5

Figure 4-7 Demonstration Cycle No. 1 & 5 Flow Diagram

TABLE 4.4 DEMONSTRATION CYCLE NO.2

STEP	TIME (HR)	STEP DESCRIPTION	DURATION (HR)
1	0	Prepare A/S Analogue	4
2	4.0	Place 4 Test Samples, 12 S/C Specimens, and Tools in Main Chamber	1/2
3	4.0	Check 4 Test Samples outside of A/S Analogue	l,
4	4.5	Check 4 Test Samples in Main Chamber	1 1 2
5 .	5.0	Close-up and Leak Check Main Chamber	1
6	6.0	Decontaminate (ETO) Main Chamber	6
7	6.0	Place 4 Test Samples and 4 S/C Specimens in Dry Heat pass through	2
8	6.5	Close-Up and Leak Check Dry Heat Pass through	1
9	7.5	Decontaminate (ETO) Dry Heat Pass through	6
10	9.0	Prepare Bio-Assay Mat'l	2
11	11.0	Sterilize Bio-Assay Mat'l in Autoclave	1
12	12.0	Assay 4 S/C Specimens in Main Chamber	1 2
13	12.5	Remove Assay Mat'l and S/C specimens through	2 1
14	13.0	Sterilize Main Chamber (Dry Heat)	40
15	13.5	Sterilize Dry Heat Pass through (Dry Heat)	40
16	50.0	Prepare Bio-Assay Mat'1	2
17	52.0	Sterilize Bio-Assay Mat'l in Autoclave	1
18	53.0	Assay 4 S/C Specimens in Main Chamber (Seal Samples for removal in Step 21)	1 2
19	53.5	Transfer 4 Test Samples and 4 S/C Specimens from Dry Heat pass through to Main Chamber	1 2
20	54.0	Assay 4 Test Specimens in Main Chamber	1/2
21	54.5	Remove Assay Mat'l and S/C Specimens through Autoclave	1 2
22	55.0	Check Test Samples in Main Chamber	1
23	56.0	Assemble Test Samples	1
24	57.0	Check Test Samples in Main Chamber	1 1 2
25	57.5	Perform 20 hour Life Test (Cascade)	2 21
26	77.5	Prepare Bio-Assay Mat'l	2
27	79.5	Sterilize Bio-Assay Mat'l and 5 S/C Specimens in Autoclave	1
28	78.5	Assay Main Chamber Contents	2
29	80.5	Remove Main Chamber contents through Autoclave	
30	81.0	END	1/2

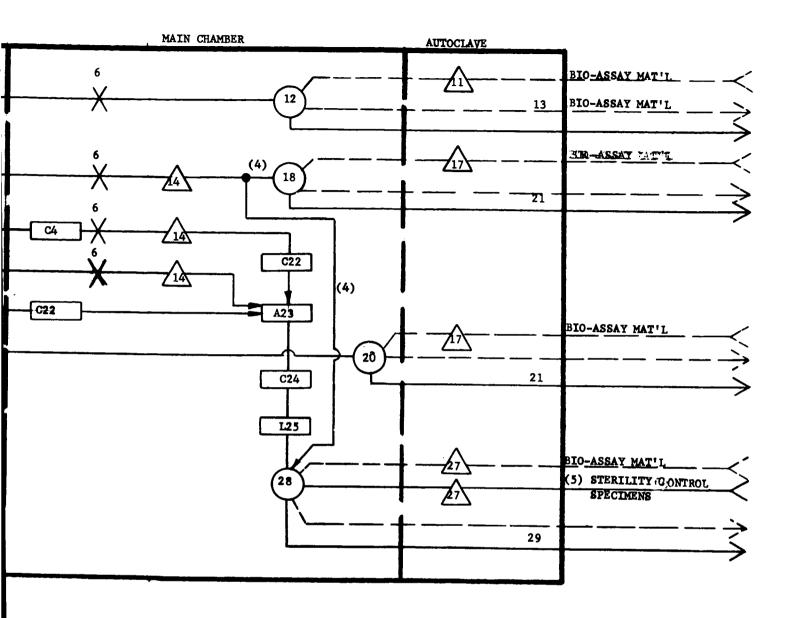
CRITICAL PATH 1,2,4,5,6,12,13,14,18 } 19,20,21,22,23,24,25,28,29,30

			ששח	UP AT	PASS-THRO
]	DKI	HEAT	PASS-IRK
>	(4) STERILITY CONTROL SPECIMENS	2			
	(0) (4)				
>	(8) CANNED STERILITY CONTROL SPECIMENS	2			
>	PARTS FOR (4) TEST SAMPLES	2	-		
	TOOLS	2			
<i>></i>	PARTS FOR (4) TEST SAMPLES	C3 }-		9 V	
· >-	(4) UNBAGGED TEST SPECIMENS			Ş X	
				/ \	رین
\/					
X	DECONTAMINATE (ETO)				
Λ	STERILIZE	•			
4					
0	BIO-ASSAY				
C	CHECK TEST SAMPLES				
A	ASSEMBLE TEST SAMPLES				

20 HOUR LIFE TEST

NOTE: NUMBERS IN PARENTHESES ARE HAR

QUANTITIES; OTHER NUMBERS ARE NUMBERS



DEMONSTRATION CYCLE #2

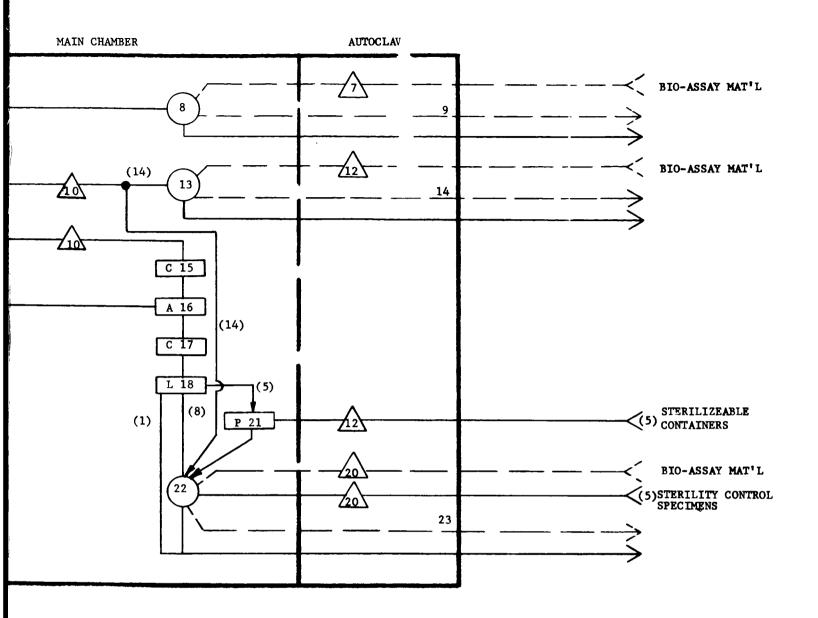
TABLE 4.5 DEMONSTRATION CYCLE WNO. 3

STEP	TIME (Hr)	STEP DESCRIPTION	DURATION (Hr)
1	0	Prepare A/S Analogue	
2	4	Place 14 Test Samples, 42 S/C Specimens, and Tools	4
		in Main Chamber	1 /0
3	4.5	Check Test Samples in Main Chamber	1/2
4	5.5	Close-Up and Leak Check Main chamber	1
5	6.5	Decontaminate (ETO) Main Chamber	1 6
6	9.5	Prepare Bio-Assay Mat'1	
7	11.5	Sterilize Bio-Assay Mat'l in Autoclave	2 1
8	12.5	Assay 14 S/C Specimens	1
9	13.5	Remove Assay, Mat'l and S/C Specimens through	1
		Autoclave	1/2
10	14.0	Sterilize Main Chamber (Dry Heat)	40
11	51 .0	Prepare Bio-Assay Mat'1	40 2
12	53.0	Sterilize Bio-Assay Mat'l and 5 Sterilizable	2
		Containers in Autoclave	1
13	54 .0	Assay 14 S/C Specimens	1
14	55.0	Remove Assay Mat'l and S/C Specimens through	1 .
	-	Autoclave	1/2
15	55.5	Check Test Samples	1 1/2
1 6	57.0	Assemble Test Samples	1 1/2
17	58.5	Check Test Samples	1 1/2
18	59.5	Perform 20 hour life test (Cascade)	21 1/2
19	79.0	Prepare Bio-Assay Mat'1	21 1/2
20	81.0	Sterilize Bio-Assay and 5 S/C Specimens	2
		Autoclave	1
21	81.0	Package 5 Test Samples in Sterile Containers	î
22	82.0	Assay Main Chamber Contents (except 1 Test Sample)	2
23	84.0	Remove Main Chamber Contents Through Autoclave	1/2
24	84.5	End	1/2

Critical Path 1, 2, 3, 4, 5, 8, 9, 10, 13, 14, 15, 16, 17, 18, 21, 22, 23, 24

			DRY HEAT PASS-THROU	GH
				_
>	(14) STERILITY CONTROL	2		
	SPECIMENS			
			,	_
	(28) CANNED STERILITY CONTROL	2		5
>	SPECIMENS			
				,
>	PARTS FOR (14) TEST SAMPLES	2		 3 c)
>	TOOLS	2		
				ß
				ł
				l •
		!		
V				
\wedge	DECONTAMINATE (ETO)			
	•	!	<u> </u>	
\wedge	STERILIZE			
				
_				
	BIO-ASSAY			
				DEMON
С	CHECK TEST SAMPLES			
	NOTE:	Numbers in hardware a	parentheses are uantities; other	
			e step numbers.	
A	ASSEMBLE TEST SAMPLES			
	20 110170 7			
L	20 HOUR LIFE TEST			

PACKAGE 10 TEST SAMPLES AND 20 S/C SPECIMENS



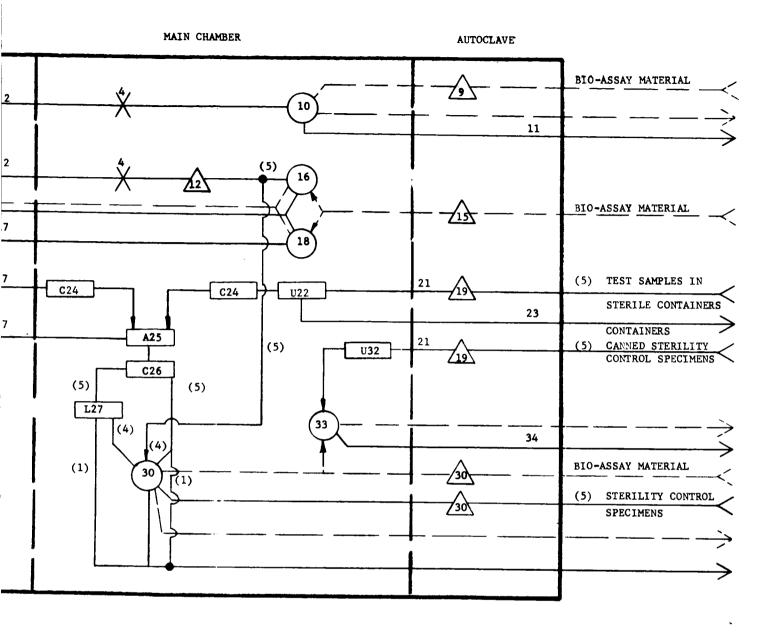
TRATION CYCLE #3

Figure 4-9 Demonstration Cycle No. 3 Flow Diagram

TABLE 4.6 - DEMONSTRATION CYCLE NO. 4

STEP	TIME (Hr)	STEP DESCRIPTION	DURATION (Hr.)
1	0	Prepare A/S Analogue	4
2	4	Place 10 S/C Specimens in main chamber	
3	4.5	Close-up and leak check main chamber	2 1
4	5.0	Decontaminate (ETO) main chamber	1 6 1
5	5.0	Place 5 test samples, 15 S/C Specimens, and tools in	1.
		dry heat pass-through	2
6	5.5	Close-up and leak check dry heat pass-through	1
7	6.5	Decontaminate (ETO) dry heat pass-through	6
8	8.0	Prepare bio-assay material	6 2 1 ½ ½ 40
9	10.0	Sterilize bio-assay material in autoclave	1
10	11.0	Assay 5 S/C Specimens	1/2
11	11.5	Remove assay material and S/C Specimens through autoclave	ž
12	12.0	Sterilize main chamber (dry heat)	40
13	12.5	Sterilize dry heat pass-through (dry heat)	40
14	49.0	Prepare bio-assay material	2
15	51.0	Sterilize bio-assay material in autoclave	1
16	52.0	Assay 5 S/C Specimens	15
17	52.5	Transfer 5 test samples, 5 S/C Specimens, and tools from	1 1 2
		dry heat pass-through to main chamber	~
18	53.0	Assay 5 S/C Specimens	1/2
19	53.0	Surface sterilize containers for 5 test samples and S/C	ī
20	53.5	Specimens in autoclave	,
20	JJ.J	Remove assay material and S/C Specimens through dry heat pass-through	2
21	54.0	Transfer test samples and S/C Specimens from autoclave to main chamber	12
22	54.5	Unpack test samples (DO NOT OPEN S/C SPECIMEN CONTAINERS)	1/2
23	55.0	Remove containers through autoclave	ž
24	55.5	Check test samples	1
25	56.5	Assemble test samples	2
2 6	58.5	Check test samples	1 2 2
27	59.0	Perform 20-hour life test on "replacement" printed circuit boards	21
28	77.0	Prepare bio-assay material	2
29	79.0	Sterilize bio-assay material and S/C Specimens in	1
		autoclave	•
30	80.0	Assay main chamber contents (except 2 test samples)	2
31	82.5	Remove main chamber contents (except the 5 S/C Specimens	1 2
		in sterile containers and unused assay material) through autoclave	2
32	83.0	Open test specimen containers	<u>}</u>
33	83.5	Assay test specimens	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
34	84.0	Remove main chamber contents through autoclave	2 1
3 5	84.5	END	-
CRITIC	AL PATH	1, 2, 3, 4, 10, 11, 12, $\overline{16}$ $\overline{18}$	
		$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	26, 27,

(5) STERILITY CONTROL SPECIMENS			
> (10) CANNED STERILITY CONTROL SPECIMENS			
(5) STERILITY CONTROL SPECIMENS	5	7	
PARTS FOR (5) TEST SAMPLES	5	X	43
> TOOLS	5	\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \	<u> </u>
			22
DECONTAMINATE (ETO)			
STERILI ZE			
BIO-ASSAY			
C CHECK TEST SAMPLES			
A ASSEMBLE TEST SAMPLES			
L 20 HOUR LIFE TEST			
U UNPACK TEST SAMPLES NOTE: NUMBERS IN PARENTHESES ARE HARDWARE QUANT	TITIES:	OTHER MIMBER	PS APF en
	,	OTHER MOMBER	O MAL S.



DEMONSTRATION CYCLE #4

EP NUMBERS.

Figure 4-10 - Demonstration Cycle No. 4 $_{\mbox{Flow}}$ Diagram

for repair are the samples removed from the chamber in sterile containers in Cycle No. 3. The main chamber is sterilized before any hardware is introduced into it. The recycled units are introduced through the autoclave and the repair units are introduced through the auxiliary chamber. After making the simulated repairs, the 20 hour life test will be performed only on the repaired units (the other units were exposed to this test in Cycle No. 3).

DEMONSTRATION CYCLE NO. 5

This cycle is identical to Cycle No. 1.

The test sample utilization for each of these cycles is shown in Table 4.7 and Figure 4-11.

The chronological flow of activities on the four tables describing the above cycles is instructive in that it illustrates the careful planning of the sequence of events which is necessary to achieve efficient utilization of the Assembly/-Sterilizer. Each of the steps must be regarded not only in flow sequence, as on the illustrations, but in time sequence, as on the tables, so that the appropriate preceding steps, some of which appear unrelated, are all performed in the order which gives greatest efficiency.

TABLE 4.7 TEST SAMPLE UTILIZATION IN DEMONSTRATION CYCLES (NOTE 1)

CYCLE NUMBER	QUANTITY PROCESSED	QUANTITY DESTRUCTIVELY BIO-ASSAYED	QUANTITY HELD FOR SUBSEQUENT USE (NOTE 3)
1	9	8	1
2	8	8	0
3	14	8	6 (Note 2)
4	10 (Note 2)	8	2
5	9	8	1

NOTES:

- (1) Test sample utilization is also shown in Figure 4-11.
- (2) 5 of the samples from cycle 3 will be removed from the A/S in containers and will be recycled in cycle 4. Thus the net quantity processed in cycle 3 and 4 is 19 and the net quantity held for subsequent use is 3.
- (3) The five samples (net) held for subsequent use will be used for program demonstration purposes showing hardware which has been processed in the A/S.

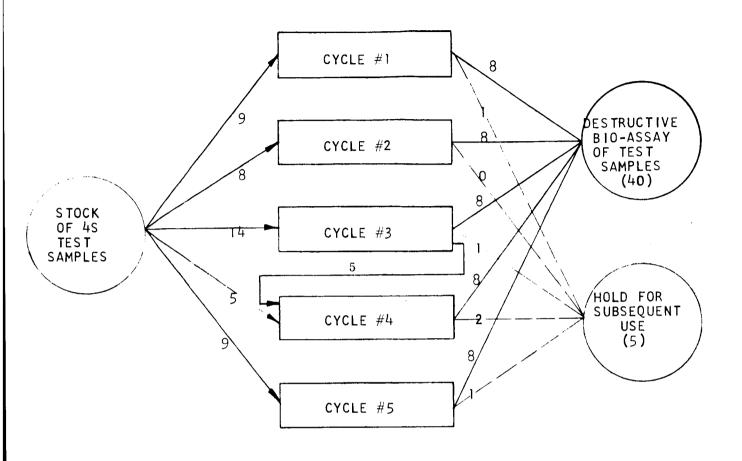


Figure 4-11 Test Sample Utilization in Demonstration Cycles

APPENDIX A - BIOLOGICAL ASSAY

I. INTRODUCTION

Biological assay (bio-assay) is an integral and essential part of the Assembly/Sterilizer Program and will consist of three major biological tasks.

- · Clean-room bio-assay
- In-Process Test Sample bio-assay
- Test and Demonstration bio-assay

The accomplishment of these tasks will provide the following:

- · Description of biological contamination in working areas
- Description of biological load on the piece parts and partially assembled test sample before introduction into Assembly/Sterilizer Analogue (A/S Analogue)
- Measurement of A/S Analogue efficiency in decontamination and sterilization cycles
- Measurement of biological integrity of A/S Analogue and employment procedure.

II. CLEAN-ROOM BIO-ASSAY

The printed circuit boards for the test sample will be assembled in a laminar flow clean-room or in laminar flow clean benches. In addition, the A/S Analogue will be installed and operated in a laminar flow clean-room.

During the periods when the test sample hardware is exposed to the clean-room environment bio-assay of the room (bench) environment will be performed. This will consist of air and fall-out sampling.

A. Air Sampling Bio-Assay

Two Reynier slit samplers will be employed to sample air in the clean-room (bench) simultaneously upstream and downstream of the work stations with respect to the horizontal laminar air flow. Samples will be taken at each location twice daily (approximately 0900 and 1500) on those days during which the room (bench) contains exposed sample materials.

The samplers will be loaded with sterilized 150 mm petri dishes containing 85 ml. of solidified trypticase soy agar. Prior to use the dishes will be incubated for 24 hours at 37°C and contaminated plates will be discarded. The sterile plates will be refrigerated at 4 to 6°C until use (not longer than 7 days).

The samplers will be placed in the clean room 2.5 to 5.0 feet above the floor. Air will be sampled at one cfm for one hour.

Upon completion of sampling, the culture dish from each sampler will be removed, covered and incubated at 32°C for seventy-two hours. The colonies will be counted after 24, 48 and 72 hours and the number of viable particles per cubic foot will be computed.

B. Fallout Bio-Assay

The degree of fallout contamination will be determined using the procedures outlined in Paragraph C, entitled "*Method of Sampling Fallout Contamination Onto Surfaces." Stainless steel test strips will be located on the assembly benches in the airflow upstream and downstream of the work and a sufficient quantity of test strips will be used to permit random selection of samples from each location during each day that the test sample hardware is exposed to the room environment.

C. Method of sampling Fallout Contamination Onto Surfaces

MATERIALS: Strips of stainless steel 1" x 2" x 0.06" (16 gauge), stainless steel pans with edges $\frac{1}{2}$ " high or less, media and glassware as required. Strips will be prepared as follows:

- 1. Wash in hot tap water with Haemo-Sol
- 2. Rinse three times in hot distilled water
- 3. Rinse in isopropanol
- 4. Rinse in ethyl ether
- 5. Drain dry
- 6. After drying, handle with forceps
- 7. Place on flat trays with enough distance between them so that they can be removed one at a time without disturbing neighboring strips.
- 8. Wrap with aluminum foil
- 9. Sterilize in dry heat at 175°C for 3 hours.
- 10. Prepare one control tray for each 10 trays prepared.

EXPOSURE: The pan and strips will be placed in the bioclean room (bench) in a location where they will not be disturbed but which will have the equivalent exposure to the air circulating in the bioclean room as prevails on bench tops where assemblies are being made.

^{*} Interim Requirements for Bio-clean Facilities, Appendix B, HQ National Aeronautics and Space Administration

ANALYSIS: At the required intervals, six strips will be removed using sterile forceps and placed into sterile square, wide-mouthed four-ounce bottles. The bottle caps will be covered with aluminum foil to prevent contamination of the lip of the bottle. The bottles containing the strips will then be transported to the laboratory and assayed within two hours after sampling.

To each bottle will be added 50 ml of sterile 1% peptone water. The sample will then be placed on a reciprocating shaker and shaken at 270 ± 5 oscillations per minute. Four 5 ml portions will then be plated in 100 mm diameter petri dishes with 20 ml of Trypticase soy agar in each.

The remainder of the sample will be heat-shocked at 80°C for 15 minutes, allowing five minutes additional heat-up time. The sample will be cooled and plated as above.

One half of the unheated and one half of the heated samples will be incubated aerobically at 32°C for 72 hours with counts at 24, 48 and 72 hours. The remainder will be incubated anaerobically at 32°C for 72 hours with counts at 72 hours only. Counts will be reported as viable count/ft², recording maximum, minimum and average values for the six strips at a given sample time.

Three to five sterile strips will be processed identically as controls at each sampling time.

Anaerobiosis will be established and maintained by H₂ replacement in Brewer anaerobic jars or equivalent. Anhydrous CaCl₂ will be placed in the bottom of each jar. Also in each jar will be placed cultures of <u>Alcaligenes faecalis</u> and <u>Clostridium sporogenes</u> as aerobic and anaerobic indicators respectively.

When the anticipated population is low, the count will be made by agar immersion as follows:

- Place a thin layer of trypticase soy agar in the bottom of a sterile petri dish and allow to solidify.
- 2. At the time of assay, place 15 ml of the plating medium into the dish and immediately immerse the stainless steel strip in the liquid agar medium.
- 3. Allow the medium to solidify and incubate at 32°C for 72 hours, counting aerobic samples at 24, 48 and 72 hours, and anaerobic samples only at 72 hours. Half of the samples will be incubated aerobically and half anaerobically as above.

III. IN-PROCESS TEST SAMPLE BIO-ASSAY

Ten sets of test sample electronic parts including the printed circuit board and five sets of mechanical parts will be subjected to bio-assay (refer to Figure B-1). Five sets of electronic parts will be assayed after cleaning and bagging and the remaining five sets will be assayed after printed circuit board assembly. The five sets of mechanical parts will be assayed after pre-assembly, heating, and bagging. Thus, the latter five sets of electronic parts and the five sets of mechanical parts will be in the condition in which they will be placed in the A/S Analogue for sterilization and final assembly.

The assay procedure for each of the parts is described in the following sections.

A. Electronic Parts

1. Piece Parts

Electronic piece parts will be assayed in the manner described in II-C for fallout strips except that the remaining fluid and the piece part itself will be totally immersed in nutrient medium according to the agar immersion method described above.

2. Printed Circuit Board

The printed circuit board will be broken aseptically into pieces less than one inch in one dimension and immersed in a sufficient volume of the sampling diluent in a 38×200 mm test tube to cover the entire sample. The assay will then be completed as described for electronic piece parts.

B. Mechanical Parts

1. Pop Rivets, Screws and Terminals

Pop rivets, screws and terminals will be assayed in the same manner as electronic piece parts.

2. Brackets

Brackets will be assayed in the same manner as electronic piece parts except that the volume of sampling diluent will be increased to permit total immersion of the brackets.

3. Structural Subassembly

The structural subassembly will be dismantled on a laminar flow clean bench for bio-assay. The heat shield material will be stripped from the skin with a sterile knife and corner braces and nuts will be removed for assay. Bio-assays will be performed as follows:

- a) <u>Heat Shield</u> The ESM will be cut aseptically into one-inch squares and each square will be immersed in sampling diluent and assayed as described for electronic piece parts.
- b) Skin The skin will be cut into one-inch strips and assayed by the technique described for the printed circuit board.
- c) Corner Brace, Nut and Nut Cage The corner brace, nut and nut cage will be disassembled and assayed by the procedure described for brackets.
- d) Thermocouple The thermocouples will be assayed in the same manner as electronic piece parts except that the volume of sampling diluent will be increased to permit total immersion of the thermocouples.

Sterile materials will be assayed by the same procedure as a control on sampling techniques.

IV. TEST AND DEMONSTRATION PROGRAM BIO-ASSAY

Bio-assay forms an integral part of the Sterilization Verification and Feasible Demonstration Tasks of the Test and Demonstration Program. The specific application of bio-assay in each of these types of tests is described in the appropriate section of the test plan.

In each of the operation cycles of the A/S Analogue, Sterility Control Specimens will be used to verify the efficacy of the prescribed decontamination or sterilization treatment. These specimens are stainless steel strips which have been seeded with known organisms. Representative test samples will also be contaminated with 1 x 10^8 spores of B. subtilis var. niger on each sample prior to introduction into the Assembly/Sterilizer.

All assays for sterility will be performed in the sterile A/S atmosphere. Sterility control specimens decontaminated with ethylene oxide will be placed into the diluent fluid in the A/S, removed, and plated for residual count in the laboratory.

The assay of test samples in the A/S Analogue will be done only at the end of a demonstration cycle (e.g. after decontamination, sterilization, checkout, assembly, checkout, and 20-hour life test have all been performed). The in-process assay of the test samples (II above) will define the base of biological contamination preceding the A/S Analogue, operations, and the S/C specimen assay will provide the measure of the efficacy of the decontamination and sterilization treatments to which the test samples were exposed. The assay of the test samples and main chamber of the A/S Analogue at the end of an operating cycle will ascertain the maintenance of A/S Analogue bio-integrity during the post-sterilization operation in the cycle.

A. Preparation of Sterility Control Specimens

Stainless steel strips measuring 1" x 2" x 0.06" will be employed as S/C specimens. Iron-constantan thermocouple junctions will be spot-welded to the undersurface of approximately one-half of the specimens. Specimens will be inoculated with an aqueous suspension of spores of either \underline{B} . subtilis var. niger or \underline{B} . stearothermophilus to produce strips with resident populations of 1×10^6 , 1×10^8 and 1×10^{10} spores. The strips will be dried at 45°C and stored in sealed containers in the room ambient atmosphere. Representative specimens will be assayed for spore population as follows:

The specimen will be placed in sterile 100 ml water blanks containing 0.05 per cent Tween 20 and shaken for five minutes on a mechanical shaker. Following shaking the resulting suspension will be diluted and plated by Standard Plate Count techniques according to Standard Methods for the Examination of Dairy Products, 11th Edition except that distilled water will be used as the diluent. Heat shocked counts will be made by heating an aliquot of the Tween 20 suspension.

 \underline{B} . subtilis var. niger will be heat shocked at 80° C for 10 minutes and \underline{B} . stearothermophilus at 100° C for 5 minutes. The plating media will be Tryptone Glucose Yeast Extract agar for \underline{B} . subtilis var. niger and Dextrose Tryptone agar for \underline{B} . stearothermophilus and incubation temperatures will be 37° C and 55° C respectively.

B. Preparation of Bacterial Spores

Bacillus subtilis var. niger will be employed as the test organism for dry heat and ethylene oxide systems. The sporulation medium will be that described by Gandin, Mular and O'Connor (1960) consisting of 0.1%, Sheffield Hy-Case SF, 0.25% glucose, 0.5% yeast extract (Difco), 0.01% MnSO4·4H₂O, 0.0001% FeSO4·7H₂O and 0.005% CaCl₂ at pH 6.8.

A starter culture will be prepared by inoculating 50 ml of the sporulation medium in a 125 ml volumetric flask from the stock culture, heat shocking at 80° C for 10 minutes, and incubating at 37° C for 24 hours. A one per cent inoculum of the resulting culture will be transferred to one liter of the sporulation medium in a 3-liter bottle equipped with a glass sparger for aeration. The mass culture will be incubated with heavy aeration until sporulation is greater than 90 per cent complete (about 4 days). Dow Corning Antifoam A will be added as necessary to prevent excessive foaming.

The culture will be refrigerated after sporulation is complete, harvested by centrifugation at 4°C, resuspended in phosphate buffer, scrubbed with ultrasonics, and washed 10 times with distilled water. The final clean spore preparation will be examined for cleanliness and refractility by phase microscopy. Bacillus stearothermophilus will be employed as the test organism for the steam sterilization system. The sporulation medium will be nutrient agar supplemented with 0.0001% MnSO4.4H20 from stock, heat shocking the subculture at 100°C for 5 minutes, and incubating at 55°C for 24 hours.

One milliliter of the starter culture will be spread over the surface of the sporulation medium on each of several petri dishes, and the resulting cultures will be incubated at 55° C in a humidified atmosphere until a high percentage of sporulation is attained (approximately 4 days). The culture will be harvested by suspending the growth in distilled water, centrifuging, and washing as described for <u>B. subtilis</u> var. <u>niger</u>.

Standard plate counts will be made of samples of the spore populations before and after heat-shocking to determine the total viable population and the population of heat-resistant spores. Appropriate dilutions will be made of the spore preparations to provide inocula for preparing Sterility Control specimens.

C. Sterilization Verification Test Bio-Assay

In the assay immediately following ETO decontamination, the Sterility Control (S/C) specimens will be immersed in sterile sampling diluent (0.05% Tween 20 and 0.1% peptone) in a 38 x 200 mm test tube and shaken on a reciprocating shaker for five minutes. The entire suspension, including the S/C specimen will then be transferred aseptically to a sterile petri dish and covered and mixed with tempered Tryptone (Glucose Yeast Extract agar).

After the agar solidifies, the petri dish will be incubated in an inverted position in a humidified atmosphere at 37 °C for seven days. The resultant colonies will be counted and recorded after two and seven days. The post-dry heat assay is the same as presented in Section D below.

D. Feasibility Demonstration Bio-Assay

In the feasibility demonstration, bio-assay will be limited to sterility tests to detect viable aerobic mesophiles (thermophiles in the case of autoclaved Sterility Control Specimens) on heat-sterilized assemblies and Sterility Control specimens. The procedure for assaying ETO test specimens will be the same as presented in Section C above.

To broaden the biological base of the experiments in the feasibility demonstration, one-half of the test samples processed in the A/S Analogue will have been previously seeded with <u>B. subtilus</u> var. <u>niger</u> using the same techniques employed for seeding of the S/C Specimens (B above). The resident, controlled microbial population will be 1×10^8 viable organisms.

After all electrical tests have been completed on the assembled "sterile" test sample, it will be disassembled in the Assembly/Sterilizer for sterility testing. Electronic piece parts will be removed by cutting the wires with sterile tools and immersed individually in the test medium. The remainder of the assembly will be dismantled as described in III B above and the resulting piece parts and fragments will be immersed in the test medium.

Sterility Control Specimens used in the feasibility demonstration will also be sterility tested by immersion in the test medium.

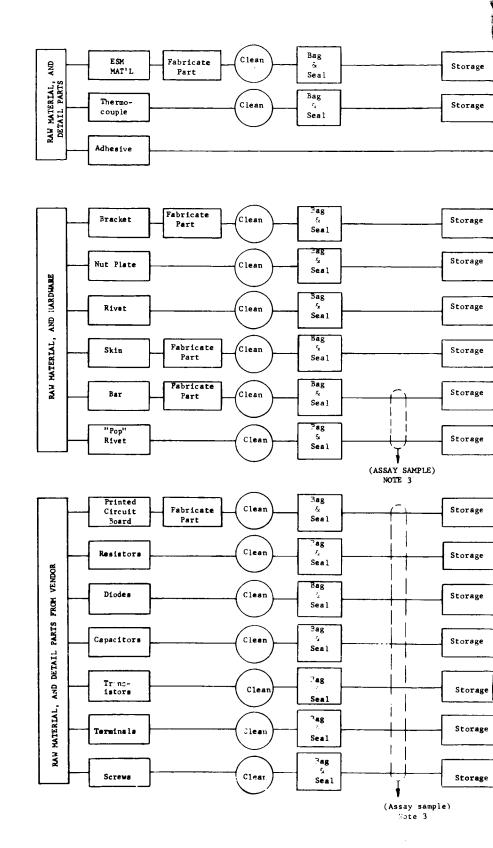
Trypticase soy broth will be employed as the sterility test medium. Sterility tests will be incubated in screw-capped test tubes at 37°C and examined for visible turbidity as an indication of growth after two and seven days incubation. Positive cultures (turbid) will be examined microscopically to confirm microbial growth and to determine the morphological characteristics of the micro-organisms for comparison to the species used to intentionally contaminate the S/C Specimens and test samples prior to sterilization.

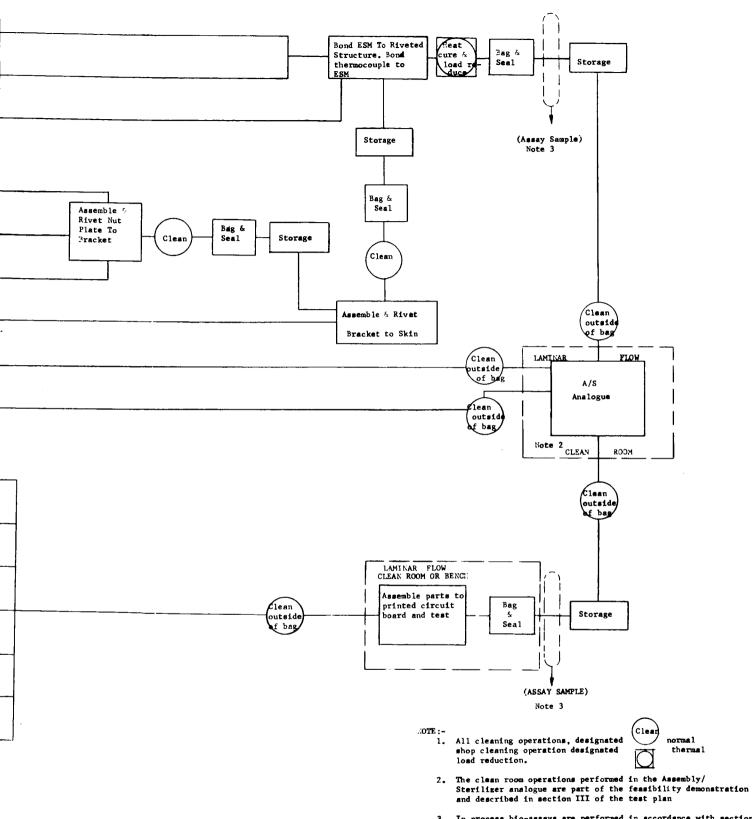
APPENDIX B. TEST SAMPLE MANUFACTURING FLOW

The test sample is a special component designed and fabricated for the feasibility demonstration. It is described in detail in Section III B 1.

Since the test sample's primary function is to provide a vehicle for organisms (natural accumulation plus controlled seeding on selected samples), it is important that the manufacturing flow for the samples be carefully planned, strictly adhered to, and subjected to appropriate biological monitoring. The attached diagram, Figure B-1, shows the manufacturing flow plan and, in particular, indicates selected bio-assay points in the flow.

Appendix A describes the techniques for bio-assay of the in-process test sample and bio-assay of the clean work areas.





 In process bio-assays are performed in accordance with section of appendix A.

Figure B-1 - Manufacturing Flow Diagram

APPENDIX C. UTILIZATION OF STERILITY CONTROL SPECIMENS

In the program a total of 281 S/C Specimens, as described in Appendix A will be employed. These will be used in the sterility verification cycles and in the verification of the efficacy of the decontamination and sterilization treatments in the feasibility demonstration. In addition, a small quantity of S/C specimens will be held for possible use by NASA Langley.

The specific uses of the specimens are described in Sections II C and III C. A summary of the quantities for each purpose is presented below in Table $C \cdot 1$.

TABLE C.1 - STERILITY CONTROL SPECIMEN UTILIZATION

OHANTT TY

PURPOSE		QUANTITI	-1
Sterility Verification Tests			
ETO Verification		60	
Dry Heat Verification		60	
Wet Heat Verification	•	30	
Hold for NASA Langley		10	
Feasibility Demonstration			
ETO Verification		41	
Dry Heat Verification		50	
Wet Heat Verification		25+5	(Note 1)
Sterility Maintenance Verification		41	•
•	TOTAL	322	
	ETO Verification Dry Heat Verification Wet Heat Verification Hold for NASA Langley Feasibility Demonstration ETO Verification Dry Heat Verification	Sterility Verification Tests ETO Verification Dry Heat Verification Wet Heat Verification Hold for NASA Langley Feasibility Demonstration ETO Verification Dry Heat Verification Wet Heat Verification Sterility Maintenance Verification	Sterility Verification Tests ETO Verification 60 Dry Heat Verification 60 Wet Heat Verification 30 Hold for NASA Langley 10 Feasibility Demonstration ETO Verification 41 Dry Heat Verification 50 Wet Heat Verification 25+5 Sterility Maintenance Verification 41

NOTE:

PURPOSE

5 of the S/C specimens are used in feasibility demonstration cycle #4 to verify that surface sterilization of a container by wet heat does <u>not</u> sterilize its contents.

A/S ANALOGUE PREPARATION

Prior to its use as a facility for sterilization, assembly and checkout of equipment, the A/S Analogue will be put through a rigorous cleaning, preparation checkoff and bio-load reduction cycle.

A. Cleaning

- 1. Open all A/S Analogue doors and remove all removable items such as racks, tools, and filters.
- 2. Scrub all external surfaces with detergent solution followed by distilled water rinse and decontamination with 70% ethanol or 70% isopropanal
- 3. Clean all removable items as in (2) above.
- 4. Clean all accessible internal surfaces, as in (2) above, working from innermost parts outward installing removable items as appropriate stages of cleaning. Close off each section as it is cleaned.

NOTE: Examine filters carefully for cleanliness and condition before installing.

B. Check-Off

The check-off procedure will be defined later.

C. Bio-Load Reduction

After cleaning and check-off, the main chamber, auxiliary chamber, and autoclave will be subjected to sterilization cycles for biological load reduction.

The load reduction cycles for the main and auxiliary chambers shall be dry heat cycles as specified below. (ETO/Freon may be employed at the option of the director of A/S Analogue operations).

The load reduction cycle for the autoclave shall be the dry load cycle described below.

II. MAIN CHAMBER OPERATION

A. Set-up and Leak Check.

1. Place equipment to be sterilized, tools, test cables, etc., in the chamber in such a manner as to maximize contact of the chamber atmosphere with the chamber contents and to minimize disturbance of the subsequent laminar flow. Connect thermocouples to the thermocouple junction panel and attach the sensing end to the equipment in the chamber. The equipment may be passed into the main chamber through the end doors, the auxiliary chamber, or the autoclave.

- 2. Close and seal the end doors of the chamber and inner doors of the auxiliary chamber and autoclave.
- 3. Initiate the laminar flow.
- 4. Purge the air from the chamber and fill it with helium to a pressure of 4" of water above ambient. Check gloves and all seams and seals for leaks using a helium leak detector or equivalent. Total leakage at any one point shall not exceed 10⁻⁵scc/sec.

B. ETO/Freon Cycle

- 1. Perform IIA. above for set-up and leak check.
- 2. Maintaining laminar flow of the chamber atmosphere, purge the helium from the chamber and fill it with ETO/Freon (12%/88%) to a pressure of 4" of water above ambient, (nominally 20 changes of gas).
- 3. Raise the chamber temperature, at a rate of 25°F. to 50°F per hour, to the preselected temperature in the range of 100°F. to 150°F., maintaining chamber pressure by bleed-off.
- 4. Maintain the selected chamber temperature for a period of 2 to 24 hours (2 hr. at 130° F., 24 hr. at 100° F.). The chamber pressure and a relative humidity of 50% to 60% shall also be maintained.
- 5. At the completion of the high temperature dwell, return chamber temperature to ambient at a rate of 25°F, to 50°F, per hour, maintaining chamber pressure by make-up with ETO/Freon.
- 6. Maintaining a positive chamber pressure, purge the ETO/Freon from the chamber and fill with sterile nitrogen to a pressure of 4" of water above ambient. (nominally 20 changes of gas). When the nitrogen atmosphere has been established, the relative humidity shall be 20% to 60% at ambient temperature. It will probably be necessary to cool the recirculating gas during the nitrogen fill to prevent overheating the chamber contents.

NOTE: It shall be possible to maintain the chamber for an extended period in the state it is left in immediately following steps 5 or 6. Chamber pressure shall be maintained by make-up with ETO/Freon or sterile nitrogen respectively.

C. Dry Heat

The dry heat cycle may be performed either after set-up and leak check or after the ETO/Freon cycle in the main chamber.

Omit steps 1 and 2 below if ETO/Freon cycle precedes dry heat.

1. Perform IIA above for set-up and leak check.

2. Maintaining laminar flow of the chamber atmosphere, purge the helium from the chamber and fill it with sterile nitrogen to a pressure of 4" of water above ambient (nominally 20 changes of gas). It may be necessary to cool the recirculating gas during the nitrogen fill to prevent overheating of chamber contents. When the nitrogen atmosphere has been established, the relative humidity shall be 20% to 60% at ambient temperature.

NOTE: Cooling required may be limited to that which will limit rate of chamber heating to 25°F. to 50°F. per hour and will prevent chamber temperature from exceeding the preselected sterilization temperature. As an operating plan this same limitation may be placed on step (6) of the ETO/Freon cycle when it is to be followed by dry heat.

- 3. Raise the chamber temperature, at a rate of $25^{\circ}F$. to $50^{\circ}F$. per hour, to the preselected temperature in the range of $70^{\circ}F$. to $300^{\circ}F$. maintaining chamber pressure by bleed-off.
- 4. Maintain the selected chamber temperature for the specified period. Typical periods are 22 hours at 275°F. and 336 hours at 221 F., when temperature is measured at the coldest point on the equipment in the chamber. At temperatures of 200°F. to 300°F., the chamber relative humidity shall be less than 1%. The chamber pressure shall be maintained, at high temperature, by make-up with sterile nitrogen.
- 5. At the completion of the high temperature dwell, return chamber temperature to ambient at a rate of 25°F, to 50°F, per hour, maintaining chamber pressure by make-up with sterile nitrogen. When the chamber has been returned to room ambient, the relative humidity of the chamber atmosphere shall be 20% to 60%.

NOTE: It shall be possible to maintain the chamber for an extended period in the state it is left in following step 5 by make-up with sterile nitrogen.

D. Shut Down

- 1. Discontinue laminar flow.
- 2. Bleed-off the chamber pressure to eliminate the pressure gradient across the door seals.
- Disconnect the thermocouple from the chamber contents.
- Shut off all main chamber equipment.
- 5. Open one end door and remove the contents of the chamber, then close the door.

III. AUXILIARY CHAMBER OPERATION

The operation of the auxiliary chamber is the same as the operation of the main chamber with the following exceptions:

- 1. The auxiliary chamber recirculating flow is not laminar.
- 2. In operation, the auxiliary chamber pressure will be 2" to 3" of water above ambient, (i.e., 1" to 2" of water below the main chamber).
- 3. Thermocouples can be removed from the contents only after the chamber door is opened.
- 4. To pass sterilized equipment into the main chamber, the auxiliary chamber pressure must be brought up to 4" of water above ambient and equalized with the main chamber pressure before opening the door into the main chamber.

IV. AUTOCLAVE OPERATIONS

There are two types of autoclave operating cycles; one for a dry load and one for a liquid load .

A. Set-Up

- 1. Place equipment to be sterilized in the autoclave in such a manner as to maximize contact of the autoclave atmosphere with the equipment. Connect thermocouples to the thermocouple junction panel and attach the sensing end to the equipment.
- Close and seal the end doors of the autoclave (applies to outer door only if inner door is already closed).

B. Dry Load Cycle

- 1. Perform A(1) and (2) above.
- 2. Let in steam and bring autoclave up to the preselected temperature in the range of $216^{\circ}F$. to $270^{\circ}F$. While steam in being admitted, monitor for steam leaks around doors and seals.
- Maintain the selected autoclave temperature for a period of 5 minutes to 3 hours nominal (5 minutes at 270°F; 3 hours at 216°F.)
- 4. Exhaust steam rapidly to ambient pressure (2 minutes nominal).
- 5. Fill the autoclave with sterile nitrogen; flush and refill with sterile nitrogen to 2" to 3" of water above ambient (nominally 20 gas changes).
- 6. Allow chamber to cool to ambient temperature maintaining chamber pressure by make-up with sterile nitrogen.

C. Wet Load Cycle

- 1. Perform A(1) and (2) above.
- 2. Purge the autoclave with steam and bring autoclave up to the preselected temperature in the range of 216°F. to 270°F. While steam is being admitted, monitor for steam leaks around doors and seals.
- 3. Maintain the selected autoclave temperature for a period of 5 minutes to 3 hours nominal (5 minutes at 270° F; 3 hours at 216° F.)
- 4. Exhaust steam slowly to 2" to 3" of water above ambient (exhaust in 8 minutes minimum, 20 minutes maximum).
- 5. Purge the autoclave with sterile nitrogen maintaining a pressure of 2" to 3" of water above ambient.
- 6. Allow chamber to cool to ambient temperature maintaining chamber pressure by make-up with sterile nitrogen.

D. Transfer to Main Chamber

- 1. Raise autoclave pressure with sterile nitrogen to 4" of water and equalize with main chamber pressure.
- 2. Open autoclave inner door and slide autoclave rack into main chamber.
- 3. Disconnect thermocouples from equipment, remove equipment from rack, and push rack and thermocouples back into autoclave.
- 4. Close and seal autoclave inner door.
- 5. Reduce autoclave pressure to ambient by bleed-off through the vacuum pump.

During the fourth quarter of the program the assay procedure for determining acutal counts achieved in seeding sterility control specimens was modified This modification added a requirement for exposing the strips to ultrasonics for five (5) minutes prior to mechanical shaking and assay as described in section IV A of Appendix A of the test plan.

Events occuring during the fifth quarter indicated the advisability of the following changes:

- 1. Deletion of the use of ETO/FREON in the main chamber.
- 2. Modification of the assay procedure for the stainless steel sterility control specimens.

The first of these changes required revision of the sterility verification and demonstration cycles. The revised cycles are shown in tables 2.1, 4.3 through 4.6, and figures 2-3, 4-7 through 4-10.*

The second of these changes was required to obtain countable plates from Sterility Control Specimens exposed to the ethylene oxide decontamination cycles. Because of the uncertainty associated with predicting the remaining viable population after ETO treatment, 0.1 and 1.0 ml samples werel plated in duplicate in addition to plating the remainder of the diluent. Initially attempts were made to plate the remaining diluent as a single sample in a 150 mm petri dish. The large volume of fluid proved awkward to handle and produced colonies too numerous to count. Therefore, subsequent determinations were made by plating the fluid in 5 ml aliquots in 100 mm diameter petri dishes, thereby obtaining countable plates.

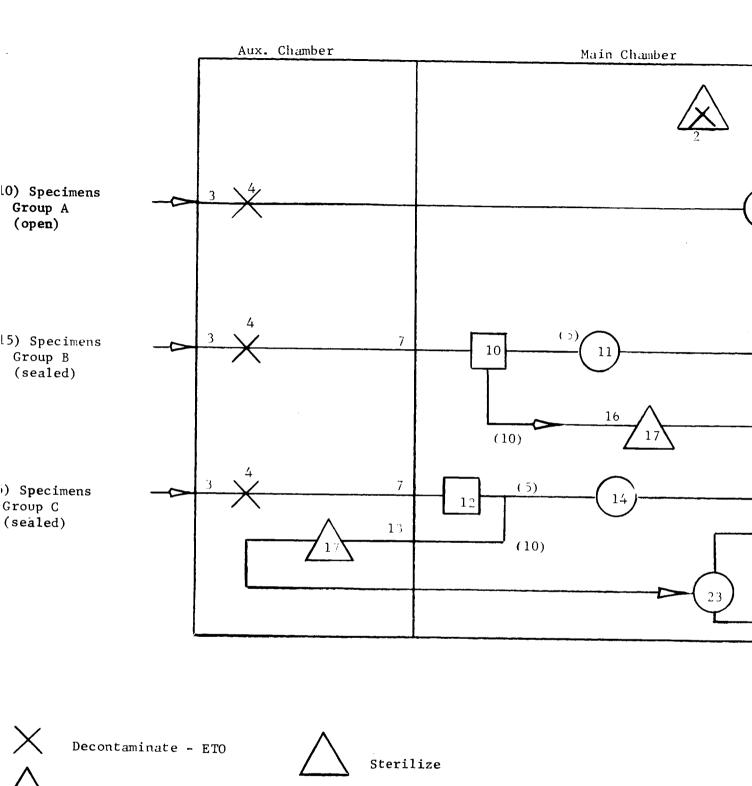
^{*}The figure and table numbers refer to the numbering of the figures and tables in the test plan Appendix B of this report, which are replaced by this material.

TABLE 2-1 - STERILIZATION VERIFICATION CYCLE

Step	Time Hr.	<u>Description</u> <u>D</u>	uration <u>Hr.</u>
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate Main Chamber	21
3.	18 3/4	Place 40 specimens in auxiliary chamber (Groups A, B, and C)	1/4
4.	19	ETO decontaminate auxiliary chamber	6
5.	22	Prepare bio-assay materials	2
6.	24	Sterilize bio-assay materials in autoclave	1
7.	25	Transfer all specimens from the auxiliary chamber to the main chamber and bio-assay material from autoclave to main chamber - do not seal doors	1/4
8.	25 1/4	Assay group A specimens (10)	1/2
9.	25 3/4	Remove group A specimens from main chamber and put them in autoclave	1/4
10.	26	Open Group B and remove 5 specimens	1/4
11.	26 1/4	Assay 5 specimens from Group B and place them in the autoclave	1/2
12.	26 3/4	Open Group C and remove 5 specimens	1/4
13.	27	Return the remainder of group C (out of the container) to the auxilian chamber and seal	1/4 ry
14.	27 1/4	Assay 5 specimens from Group C and place them in the autoclave	1/2
15.	27 3/4	Seal inner autoclave door and remove assayed specimens	1/2
16.	28	Lay out specimens from Group B in main chamber	1/4
17.	28 1/4	Sterilize auxiliary and main chambers	36
18.	61 1/4	Prepare bio-assay material	2

TABLE 2-1 Continued

19.	63 1/4	Sterilize bio-assay material in autoclave	1
20.	64 1/4	Transfer bio-assay material to main chamber & seal autoclave	1/4
21.	64 1/2	Sterilize 10 specimens (Group D) in autoclave	1
22.	64 1/2	Assay Group B specimens	1/2
23.	65	Transfer group C to main chamber and assay group C specimens	1/2
24.	65 1 /2	Transfer Group D specimens from auto- clave to main chamber	1/4
25.	65 3/4	Assay Group D specimens	1/2
26.	66 1/4	Remove all contents from main chamber through autoclave - do not open outer door till inner door is sealed	1/2
27/.	66 3/4	End of test.	

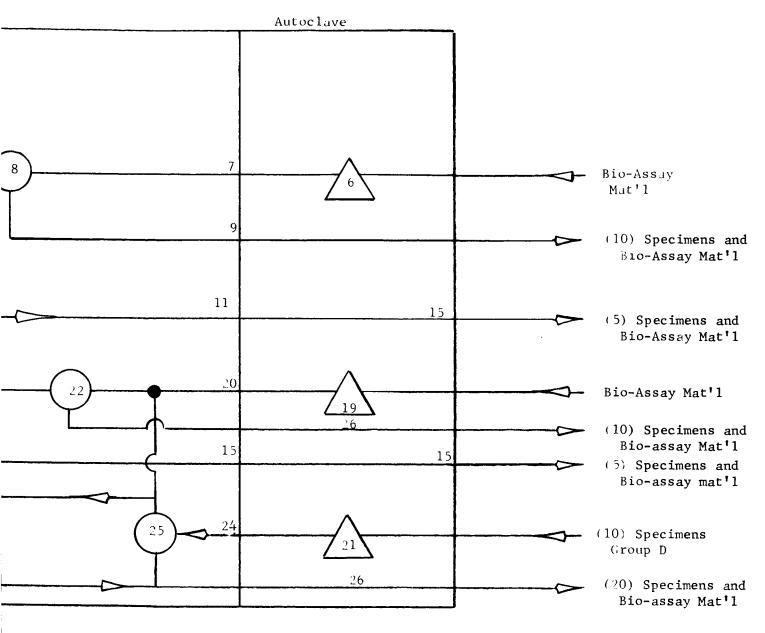


Decontaminate - Dry Heat

Open Container

Assay

STER

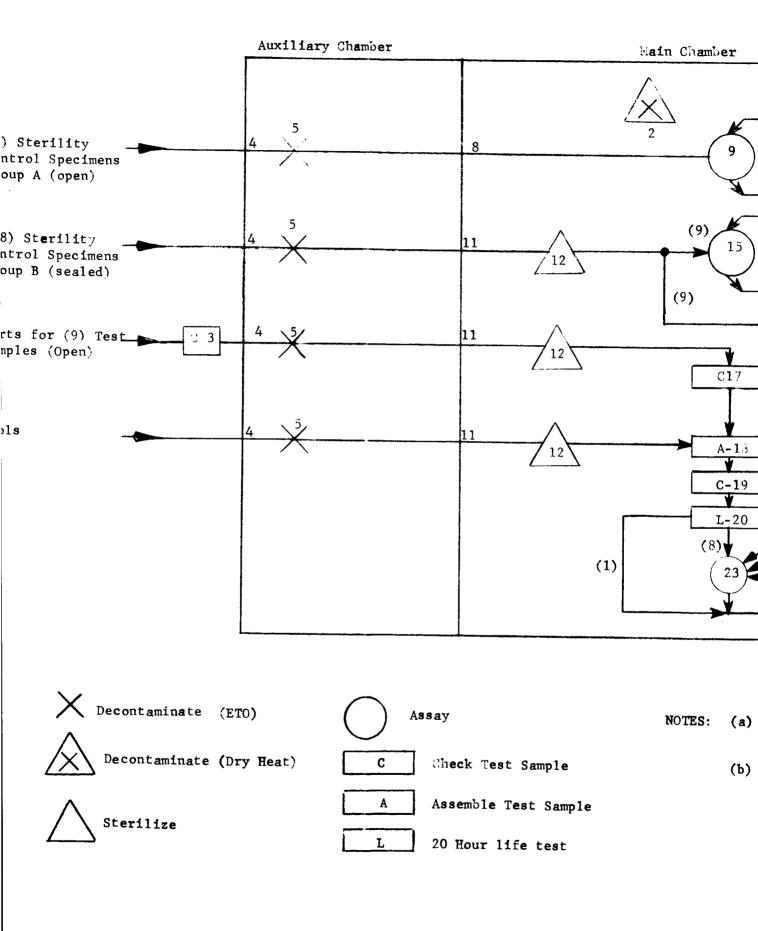


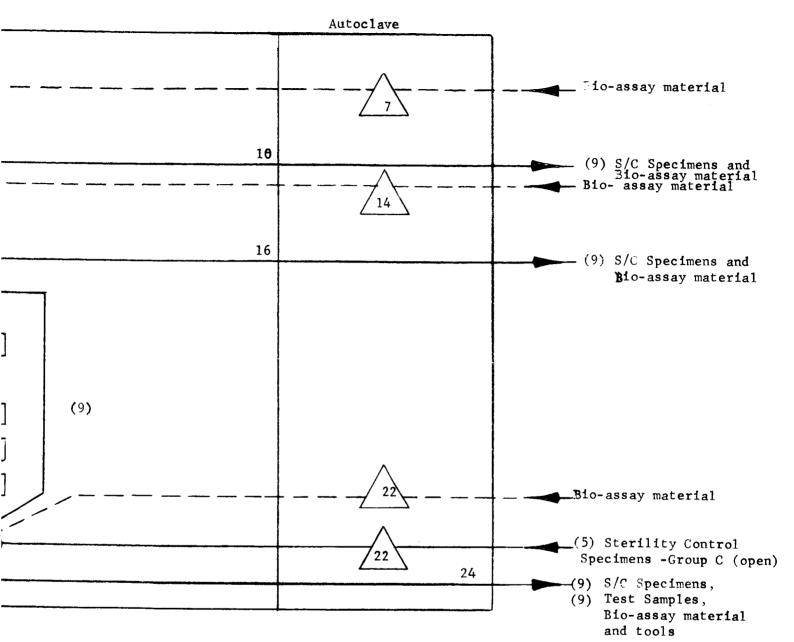
- NOTE: (1) Numbers in parentheses are specimen quantities other numbers are step numbers.
 - (2) Specimen groups A, B, & C seeded with B. subtilis var niger; group D seeded with B. stearothermophilus

TABLE 4.3 DEMONSTRATION CYCLE NO. 1 & 5

<u>EP</u>	TIME (Hr)	STEP DESCRIPTION	DURATION (Hr)
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate Main Chamber	21
3.	18 1/4	Check test samples prior to introduction to auxiliary chamber	1/2
4.	18 3/4	Place (9) test samples, (27)S/C specimens, and tools in auxiliary chamber	1/4
5.	19	ETO decontaminate auxiliary chamber	6
6.	22	Prepare bio-assay material	2
7.	24	Sterilize bio-assay material in autoclave	1
8.	25	Transfer Group A S/C Specimens (9) from auxiliary chamber to main chamber	1/4
€.	25 1/4	Assay Group A S/C Specimens (9)	1/2
).	25 3/4	Remove Group A S/C Specimens (9) through auto- clave and seal autoclave inner door	1/4
L •	26	Transfer Group B S/C Specimens (18) from auxiliary chamber to main chamber, open containers, and lay specimens out in main chamber; Transfer test sample parts and tools from auxiliary chamber to main chamber, and lay out in main chamber; Seal auxiliary chamber inner door.	1
.	27	Sterilize main chamber	36
	60	Prepare bio-assay material	2
	62	Sterilize bio-assay material in autoclave	1
	63	Assay (9) S/C Specimens from Group B	1/2
	63 1/2	Remove (9) assayed S/C Specimens from main chamber through autoclave; seal autoclave inner door.	1/4
	63 3/4	Check test samples	1
	64 3/4	Assemble test samples	1

19.	65 3/4	Check Test Samples	1/2
20.	66 1/4	Perform 20 hour life test (cascade)	21
21.	84 1/4	Prepare bio-assay material	2
22.	86 1/4	Sterilize bio-assay material and (5) S/C specimens (Group C) in autoclave	1
23.	87 1/4	Assay main chamber contents (except 1 test sample)	2
24.	89 1/4	Remove all contents from main chamber through autoclave - do not open outer door till inner door is sealed.	1/2
25.	89 3/4	End of Test	





Numbers in parentheses are hardware quantities; other numbers are step numbers.

S/C Specimen groups A and B seeded with

B, subtilis var niger; group C seeded with

B. stearothermophilus

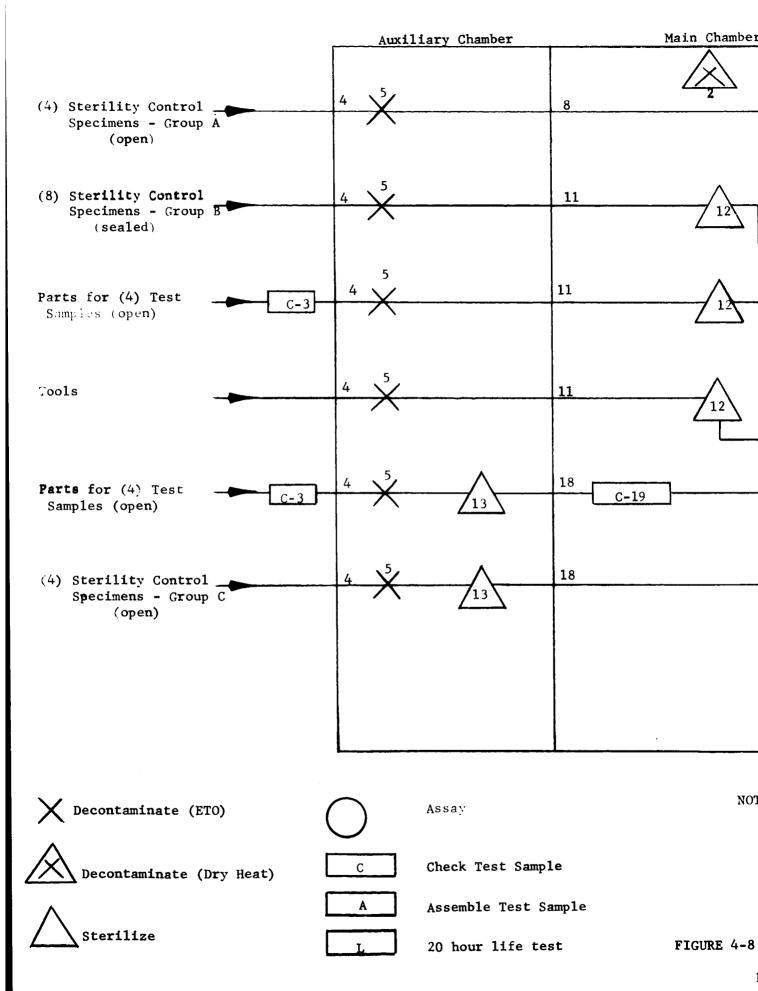
FIGURE 4-7 DEMONSTRATION CYCLE NO. 1 and 5

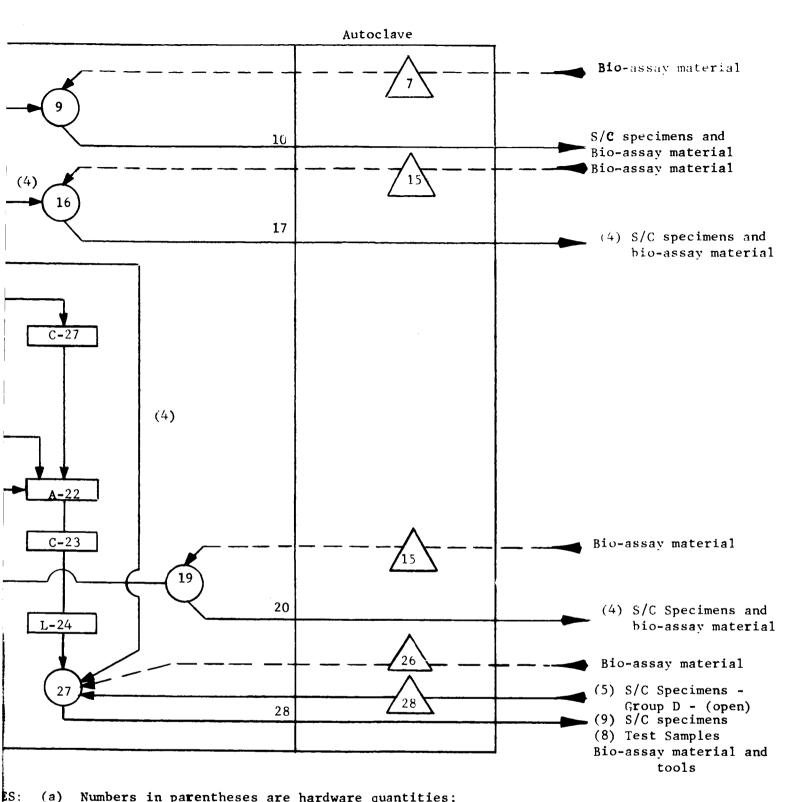
FLOW DIAGRAM

TABLE 4.4 DEMONSTRATION CYCLE NO. 2

STEP	$\frac{\texttt{TIME}}{(\texttt{Hr})}$	STEP DESCRIPTION	DURATION (Hr)
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate Main Chamber	21
3.	18 1/4	Check test samples prior to introduction to auxiliary chamber	1/2
4.	18 3/4	Place (8) Test Samples, (16) S/C Specimens, and tools in the auxiliary chamber	1/4
5.	19	ETO Decontaminate auxiliary chamber	6
6.	22	Prepare bio-assay material	2
7.	24	Sterilize bio-assay material in autoclave	1
8.	25	Transfer Group A S/C Specimens (4) from auxiliary chamber to main chamber	1/4
9.	25 1/4	Assay Group A S/C specimens (4)	1/2
10.	25 3/4	Remove assayed S/C specimens (4) through autoclave and seal inner door	1/4
11.	26	Transfer Group B S/C specimens (8) from auxiliary chamber to main chamber, open containers, and lay specimens out in main chamber; transfer parts for (4) test samples and tools from auxiliary chamber to main chamber, and layout in main chamber; seal auxilia chamber inner door.	
12.	27	Sterilize main chamber	36
13.	27 3/4	Sterilize auxiliary chamber	36
14.	60	Prepare Bio-assay material	2
15.	62	Sterilize bio-assay material in autoclave	1
16.	63	Assay (4) S/C specimens from Group B	1/2
17.	63 1/2	Place (4) assayed specimens in autoclave; do not seal	1/4

18.	63 3/4	Transfer (4) Test samples, tools, and (4) S/C Specimens - Group C - from auxiliary chamber to main chamber; seal auxiliary chamber inner door.	1/4
19.	64	Assay (4) S/C specimens from group C	1/2
20.	64 1/2	Remove (4) assayed S/C specimens through auto- clave, and seal inner door.	1/4
21.	64 3/4	Check test samples in main chamber	1
22.	65 3/4	Assemble Test Samples	1
23.	66 3/4	Check Test Samples in main chamber	1/2
24.	67 1/4	Perform 20 hour life test (cascade)	21
25.	85 1/4	Prepare bio-assay material	2
26.	87 1/4	Sterilize bio-assay material and (5) S/C specimens - Group D - in autoclave	s 1
27.	88 1/4	Assay main chamber contents	2
28.	90 1/4	Remove all contents from main chamber through autoclave - do not open outer door till inner door is sealed.	1/2
29.	90 3/4	End of test	





(a) Numbers in parentheses are hardware quantities; other numbers are step numbers.

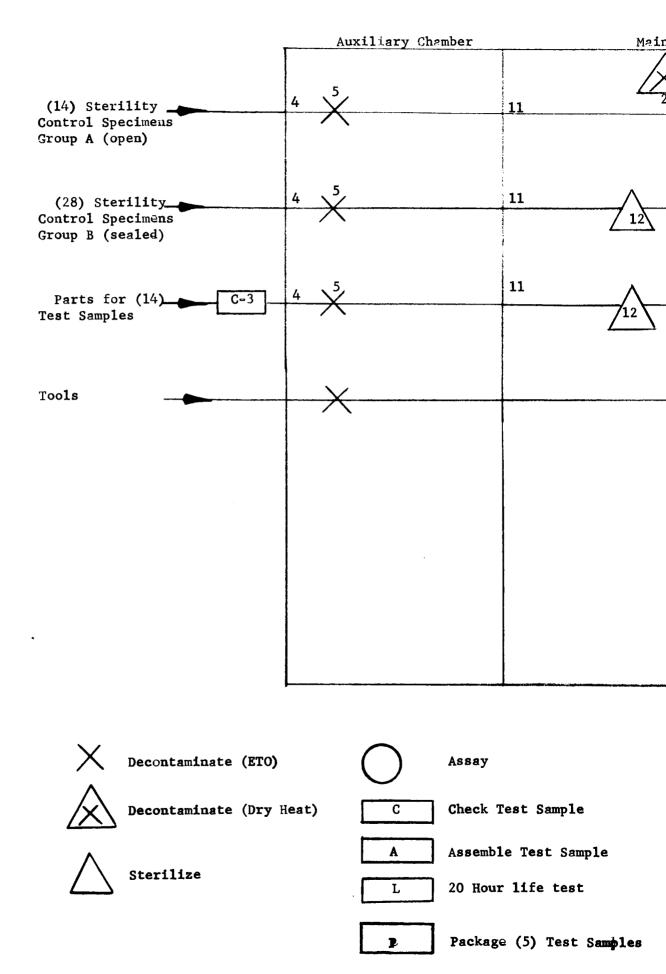
(b) S/C Specimens in groups A, B, & C seeded with B. subtilis var niger; group D seeded with stearothermophilus.

DEMONSTRATION CYCLE NO. 2

TABLE 4.5 DEMONSTRATION CYCLE NO. 3

ГЕР	TIME (Hr)	STEP DESCRIPTION	DURATION (Hr)
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate Main Chamber	21
3.	18 1/4	Check test samples prior to introduction to auxiliary chamber	1/2
4.	18 3/4	Place (14) test samples, (42) S/C specimens, and tools in auxiliary chamber	1/4
5.	19	ETO decontaminate auxiliary chamber	6
6.	22	Prepare bio-assay material	2
7.	24	Sterilize bio-assay material in autoclave	1
8.	25	Transfer Group A S/C Specimens (14) from auxiliary chamber to main chamber	1/4
9.	25 1/4	Assay Group A S/C Specimens (14)	1/2
0.	25 3/4	Remove Group A S/C Specimens (14) through autoclave and seal autoclave inner door	1/4
1.	26	Transfer Group B S/C Specimens (28) from auxiliary chamber to main chamber, open containers, and lay specimens out in main chamber; Transfer test sample parts and tools from auxiliary chamber to main chamber, and lay out in main chamber; Seal auxiliary chamber inner door.	1
2.	27	Sterilize main chamber	36
3.	60	Prepare bio-assay material	2
4.	62	Sterilize bio-assay material and sterilize- able containers in autoclave	1
5.	63	Assay (9) S/C Specimens from Group B	1/2
5 .	63 1/2	Remove (9) assayed S/C specimens from main chamber through autoclave; seal autoclave inner door.	1/4
	63 3/4	Check test samples	1
	64 3/4	Assemble test samples	1

19.	65 3/4	Check Test Samples	1/2
20.	66 1/4	Perform 20 hour life test (cascade)	21 1/2
21.	88 3/4	Prepare bio-assay material	2
22.	87 3/4	Sterilize bio-assay material and (5) S/C specimens (Group C) in autoclave	1
23.	87 3/4	Package (5) Test Samples in sterile container	s 1
24.	88 3/4	Assay main chamber contents (except 1 test sample)	2
25.	90 3/4	Remove all contents from main chamber through autoclave - do not open outer door till inner door is sealed.	
26.	91 1/4	End of test	



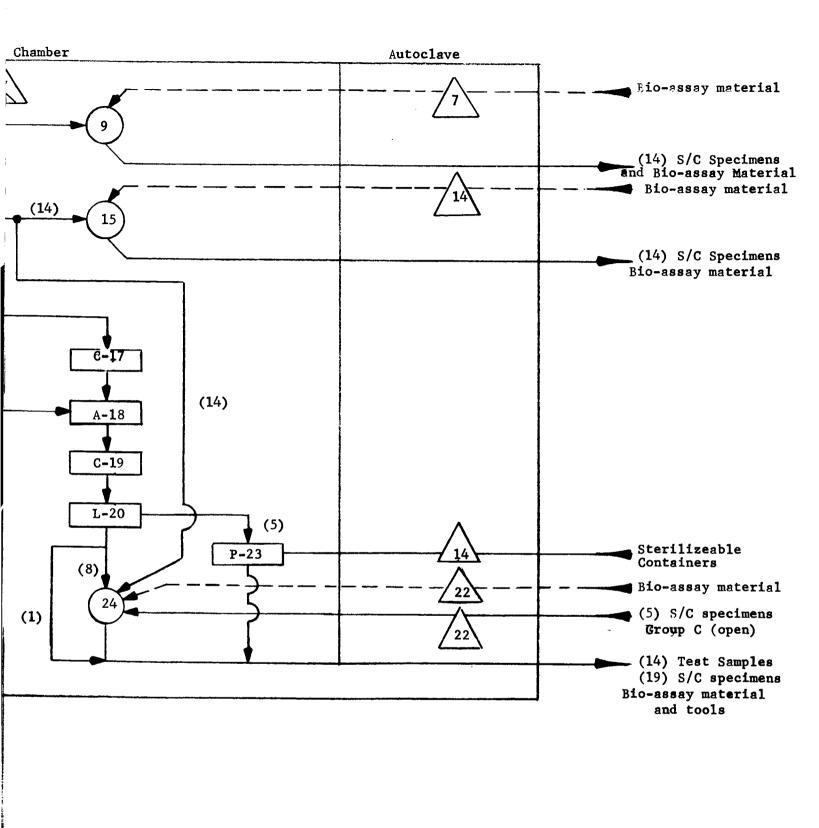
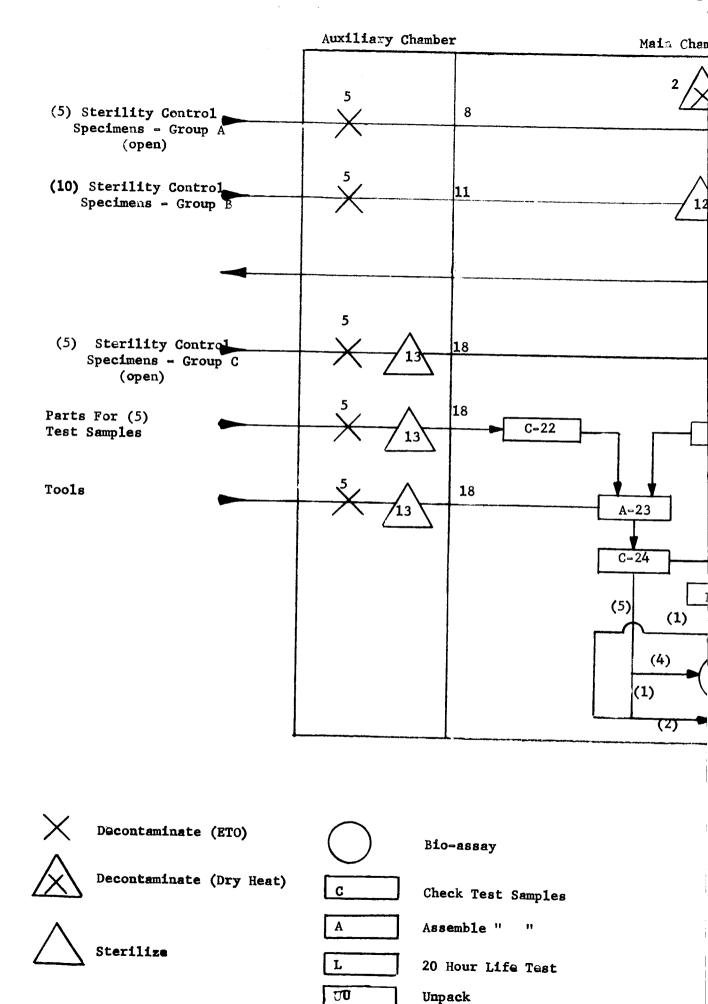


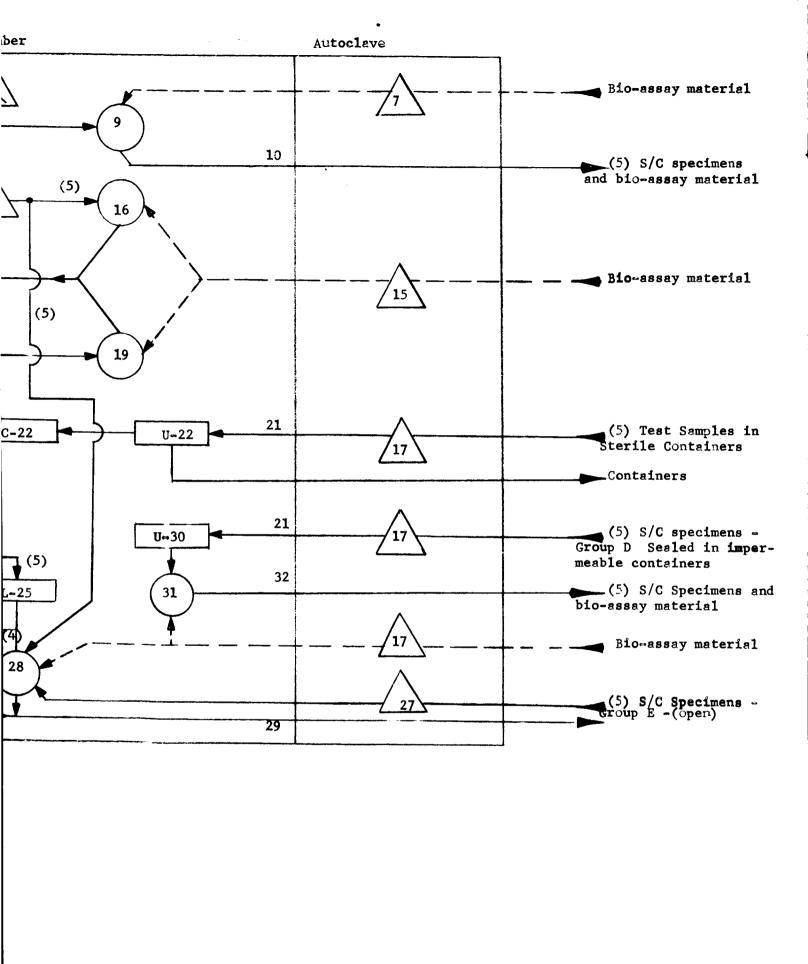
FIGURE 4-9 DEMONSTRATION CYCLE NO. 3

TABLE 4.6 - DEMONSTRATION CYCLE NO. 4

<u>EP</u>	TIME (Hr)	STEP DESCRIPTION	DURATION (Hr)
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate main chamber	21
3.	18 1/4	Check test samples prior to introduction to auxiliary chamber	1/2
4.	18 3/4	Place (5) Test Samples, (20) S/C Specimens and tools in auxiliary chamber	1/2
5.	19	ETO Decontaminate auxiliary chamber	6
5.	22	Prepare bio-assay material	2
7.	24	Sterilize bio-assay material in autoclave	1
3.	25	Transfer Group A S/C specimens (5) from auxiliary chamber to main chamber - do not seal inner door.	1/4
€.	25 1/4	Assay Group A S/C specimens (5)	1/2
).	25 3/4	Remove assayed S/C specimens (5) through autoclave and seal autoclave inner door	1/4
L.	26	Transfer Group B S/C specimens (10) from auxiliary chamber to main chamber, open containers, and lay specimens out in main chamber; and seal auxiliary chamber inner door.	1/4 n-
2.	26 1/4	Sterilize main chamber	36
3.	26 3/4	Sterilize auxiliary chamber	36
۱.	59 1 :/4	Prepare bio-assay material	2
; .	61 1/4	Sterilize bio-assay material in autoclave	1
.	62 1/4	Assay (5) S/C specimens from Group B	1/2
	62 1/2	Surface sterilize containers containing (5) test samples and (5) S/C specimens - Group D - in the autoclave	1

18.	62 3/4	Transfer Group C S/C specimens (5) from auxiliary chamber to main chamber - do not seal auxiliary chamber inner door	1/4
19.	63	Assay Group C specimens (5)	1/2
20.	63 1/2	Remove (10) assayed S/C specimens from Groups B and C through the auxiliary chamber, transfer (5) test sampkes, and tools to main chamber; do not open auxiliary chamber outer door till inner door is sealed.	1/2
21.	63 1/2	Transfer (5) Test Samples amd (5) S/C specimens - Group D - from the autoclave to the main chamber; seal autoclave inner door: DO NOT OPEN S/C SPECIMEN CONTAINERS	1/4
22.	64 3/4	Check test samples	1
23.	65 3/4	Assemble Test Samples	1 1/4
24.	67	Check Test Samples	1/2
25⊾	67 1/2	Perform 20 hour life test on "replacement" printed circuit boards (5).	21
26.	85 1/2	Prepare bio-assay material	2
27.	87 1/2	Sterilize bio-assay material and (5) S/C specimens - Group E - in autoclave	1
28.	88 1/2	Assay (8) test samples and (10) S/C specimens from groups B and E $$	2
29.	90 1/2	Remove main chamber contents, except group D S/C specimens and unused bio-assay material through autoclave - do not open autoclave outer door until inner door is sealed.	, 1/2
30.	91	Open containers containing (5) Group D S/C specimens	1/4
31.	91 1/2	Assay group D S/C specimens	1/2
32.	91 3/4	Remove main chamber contents through auto- clave	1/4
33.	92	End of test	





APPENDIX D: MANIPULATION TESTING

1.0 INTRODUCTION

1.1 PURPOSE

The primary purpose of the Manipulation test, as part of the Assembly/Sterilizer Test Program, was to study the human factors involved when physical limitations were placed on an individual performing work tasks in the Analog. A secondary objective was to perform a preliminary investigation of tools suitable for sterile assembly objective.

2.0 STUDY DESIGN

2.1 TEST PHASES

The Manipulation Test study was divided into 3 phases to permit a wider range of work tasks to be studied than would have been possible if all tests were performed in the Analog. Available Analog time was limited due to other tests being run as part of the Assembly/Sterilizer Program. The three phases were:

- 1. Work on typical flight hardware outside the Analog.
- 2. Work on Test Samples outside the Analog.
- 3. Work on flight hardware and test samples in the Analog.

Performance of the three phases in the order listed permitted a natural sequence of testing.

Phase 1 was established to meet the requirements of the Assembly Sterilizer Test Plan with work on typical flight hardware, and to initiate investigation of a variety of tools under simulated sterile conditions.

Phase 2 duplicated the conditions of Phase 1 with different assembly tasks; specifically, assembly of the Test Sample. This also provided training for the operator in assembling test samples which facilitated later work in the Analog during the feasibility demonstration tests.

Phase 3 consisted of the repetition of selected tasks from the previous two phases in the Assembly/Sterilizer Analog.

2.2 TEST CONDITIONS

To determine the effects of work circumstances, data was collected under four conditions:

- A. Unrestricted work on an open bench
- B. Work on an open bench while wearing gloves

- C. Work performed in an Analog simulator (Mock-up)
- D. Work performed in the Assembly/Sterilizer Analog

The manipulation test was primarily intended to study work performed under condition D. Condition A provided basis for comparison between normal working procedures and work under more restrictive conditions. Conditions B and C were added to provide a transition from Condition A to D with progressively more restriction while permitting an early study of factors inherent in work in the Analog.

2.3 TASK SELECTION

From a wide selection of operations normally performed in the assembly of aerospace hardware, twenty-one tasks were selected and incorporated into the final test plan. These tasks were chosen so that an operator's performance could be evaluated for the following criteria:

- . Use of a wide range of common tools.
- . Use of various sized fasteners.
- Installation of several types of components, requiring different work techniques of varying degrees of difficulty.
- . Performance of progressively more complicated work.
- . Performance under progressively more restrictive circumstance.

The tasks selected are listed below:

- 1. Assemble bracket to chassis
- 2. Assemble bracket to chassis
- 3. Assemble bracket to chassis
- 4. Assemble bracket to chassis
- 5. Assemble bracket to chassis
- 6. Assemble bracket to chassis
- 7. Assemble Hubbel Connector to Chassis
- 8. Connect 5 wires to 5 other components from Amphenol Connector
- 9. Connect 2 plugs from chassis to Baroswitch connectors
- 10. Assemble fuse holder, gasket, locknut, fuse and cap to chassis
- 11. Assemble Relay to Chassis

- 12. Connect 10-pin Amphenol Plug into Socket
- 13. Connect 10-pin Amphenol Plug into Socket
- 14. Gather 5 wires, Clamp; Assemble Clamp to Chassis
- 15. Make Complete Assembly 5 cycles.
- 16. Assemble Printed Circuit Board to Bracket Test Sample
- 17. Assemble 1 Bar to Bracket on Test Sample
- 18. Assemble and Rivet Bar to Bracket
- 19. Assemble Test Sample by: (1) Assembling bar to bracket;(2) Installing Circuit Board
- 20. Repeat task # 4
- 21. Repeat task # 10

The work tasks ranged from operations as simple as attaching an L-shaped bracket to the chassis with various sized screws (Figure D1) to a task as complicated as complete assembly of a chassis and parts. This latter task required installation of seven components and wiring the components. All wiring was done using screws and ring tongue lugs because soldering is not to be performed in the Analog. The assembled chassis is shown in Figure D2. Two tasks (tasks 20 and 21) were repeated at the end of the tests to determine if the operator's skill increased significantly during the course of experiments.

Tasks 7 and 11 were selected to determine the operator's ability to work in constricted locations. The parts used in the tasks were a "Hubbel connector" and a "relay". The Hubbel connector was chosen because it is attached to the chassis with three screws, one of which is obstructed by the body of the connector and the corner of the chassis. This is shown in Figure D3. The relay was chosen because the nuts holding it on the chassis are attached to study that are recessed in small wells in the body of the relay. The relay is shown in Figure D-4. Its assembly is shown in Figure D5. It was felt that performance of these two tasks would be a good measure of the operator's dexterity while wearing gloves.

Tasks 16 through 19 were chosen to give the operator training in working with the test sample as well as to test his skill with the tools and procedures involved in the assembly. Figures D-6 and 7 show the test sample and the tools used in its assembly. (All the tools shown in figure D6 will withstand the sterilization and decontamination cycles).

Most of the parts used for the tests were already assembled in an electronic chassis used for testing purposes. The chassis and parts were chosen for use in the tests because the chassis



Figure D=1 - Installing Bracket

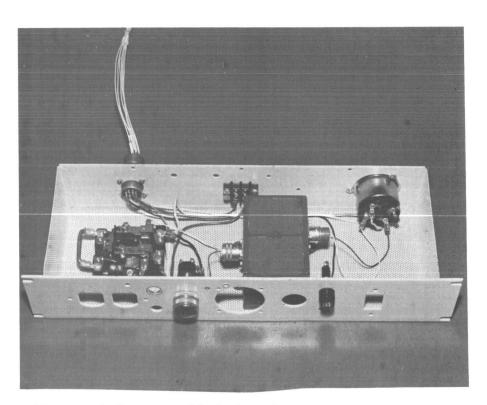


Figure B-2 - Assembled Chassis

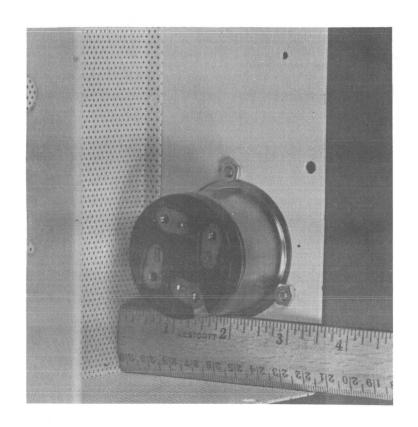


Figure D~3 - Hubbel Connector

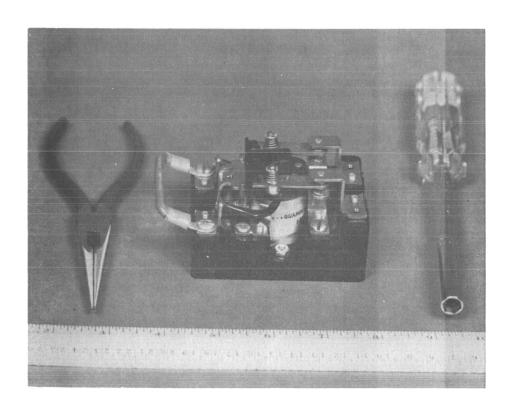


Figure D-4 - Relay and Assembly Tools



Figure D-5 - Installing Relay

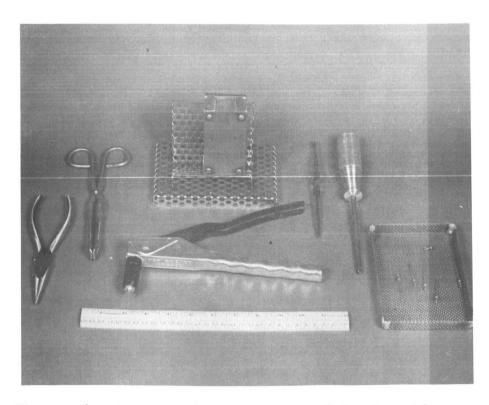


Figure D-6 - Test Sample and Tools Used for Assembly

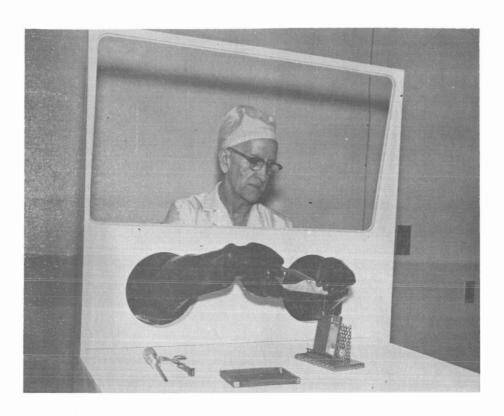


Figure D-7 - Using Pop Rivet Tool on Test Sample

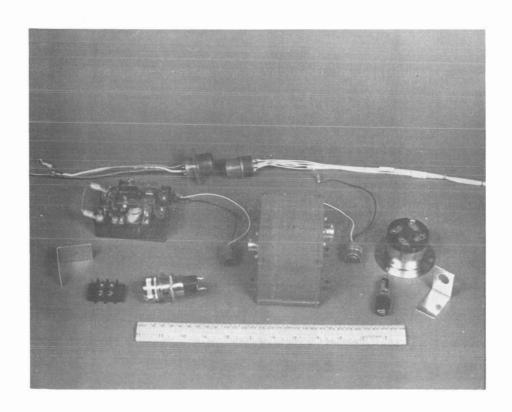


Figure D-8 - Components Used

was representative of a section of vehicle structure to which parts must be assembled and the parts were similar to flight hardware. A set of brackets was fabricated to be used in simple tasks. The parts are pictured in Figure D8. Finally, the parts of a test sample were used for a portion of the tasks.

2.4 TOOL SELECTION

The tools that were used were determined by inventorying a well stocked box belonging to the foreman of a final assembly shop. A representative selection of tools was then chosen from the inventory. Particular care was taken to choose tools that the foreman felt were necessary equipment, although other items were also included to broaden selection. A few tools were added during the course of testing when their need became evident. The tools used are illustrated in Figure D9.



Figure D-9-Tools Used

A list of the tools illustrated in Figure D91s shown below in Table DI. Unless otherwise noted the tools were made of common tool materials. For example, screwdrivers had nickel-steel shanks and plastic handles.

TABLE D-I

Socket Wrenches with Ratchet (1/4" drive)

Socket Size: 3/4", 1/4", 3/16" std. Socket Size: 1/4", 5/16, deep well

Nut Driver

Adjustable Wrenches: 6" and 10"

Phillips Head Screwdriver: Aluminum Handle and beryllium - copper Alloy Shank

No. 2; 1 1/2" shank, 5" shank

No. 1; 3" shank No. 1; 1" shank

Box End Wrench: 7/16"

Open End Wrench: 3/4", 11/16" (thin wall), 5/16", 1/4"

Straight Blade Screwdriver"

1/4" blade, 4" shank and 6" shank

Cleco Fastener Tool

Pop Rivet Tool: 3/32" collet

Offset Pliers

Slim Nose Pliers, beryllium - copper alloy.

Tongs 7" (surgical steel)

Tweezers: 6 3/4" (chrome plated)

Screwdriver/Starter:

1/4" blade, 1 1/2 shank #1 Phillips Head, 2 shank

Screw Starters:

Phillips Head: 2" and 4" Slot Head: 2" and 4"

Magnetic Pick-up Tool

3 x 5 Mirror

Parts Trays, stainless steel (Figure D-7)

Fixture, stainless steel (Figure D-7)

Fasteners were selected in much the same manner as tools. The attendant in a parts crib was asked to provide a selection of one each of the standard size screws he normally issued. This selection was then refined to give a representative selection of screw sizes, threads, lengths and head types. In the final selection screw sizes ran from #2 Phillips head screw and nut to a one-half inch hex head bolt. Allen head screws, slot head screws, cleco fasteners and pop rivets for the test sample were also used.

2.5 OPERATOR SELECTION

2.5.1 Number of Operators Required

Only one operator was used to perform all tasks. The decision to use one rather than several operators was made for the following reasons:

- Use of one operator kept data consistent and allowed easier comparison of results.
- Preliminary work outside the Analog was good training for the person who performed assembly tasks in the Analog.

The use of one operator made comparison of tasks simplier and more meaningful because the operator's attitude and ability remained nearly constant factors throughout. With several operators it would have been necessary to duplicate tasks so that individual differences could have been factored out. This was not considered feasible because the time and cost involved in conducting multi-operator tests would have been far greater than that established by the test plan.

The training received by the operator while performing the tests was a valuable aid in operating the Analog. During the Manipulation Test the operator was oriented in the concepts and operation of the system as well as actually performing sterile type assembly work. Only the operator chosen to run the Analog did assembly work in it.

2.5.2 Operator Requirements

Requirements for personality, work traits and physical size of the operator were established to aid in selecting a man who could both complete the tasks satisfactorily and to allow some extrapolation of results. The main requirements established were:

- . Correct Height.
- Average work rate and skills.
- . Patience and stability.

Correct operator height was considered essential because the center point of the arm holes in Analog is 44 inches from the floor. A rough check prior to the start of testing showed that operators over 5'10" or less than 5'4" would have problems working in the Analog. It was, therefore, desirable that the operator chosen be between 5'6" and 5'8". The operator actually employed was 5'6 3/4" tall so this requirement was well met.

Average work rate and skills were necessary so that the operator's performance could be generalized upon to some extent in drawing conclusions. The operator chosen was actually somewhat above average in his abilities.

Pre-selection of a patient and stable operator was necessary to ensure that testing could be completed without the operator becoming so frustrated that he would request reassignment midway in the tests. If this had happened, much of the value of the tests would have been lost unless work was repeated. Although selection of a stable operator created some bias in results, it was felt that this was a small price to pay compared with the alternative of interrupting the tests. The operator maintained good composure throughout the tests although in one or two cases (notably tasks 2 and 20) he did become quite agitated.

No elaborate procedure was used to select the operator. Instead, the requirements were given to the manager and foreman of the Assembly Shop and they selected the man whom they felt would best fit the requirements. The operator who was chosen worked out well.

2.6 GLOVE BOX SIMULATOR (MOCK-UP)

The panel used to simulate the Analog is shown in Figure 10. Its dimensions were kept as close as possible to appropriate the Analog dimensions. The following are the same for both the Simulator and the Analog.

- . Height of work surface (38")
- . Depth of work surface (24")
- . Height to center of armholes (44")
- . Armhole diameter (8")
- . Distance between armholes, center to center (18")
- . Angle of the viewing panel from the vertical (10°).

The main differences between the Simulator and the Analog are:

- . The back and the sides of the Simulator are open, the Analog is closed.
- . The working surface of the Simulator is flat, the Analog has a $1/2" \times 1"$ lattice to permit gas flow.
- . There is approximately 34% less working area in the simulator "Mock-up" than in the Analog. Due to doors and flanges protruding into Analog chamber.

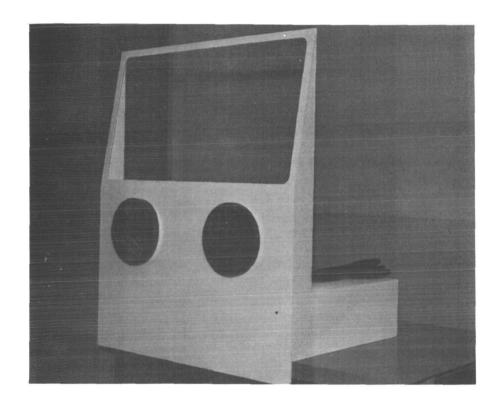


Figure D-10-Glove Box Panel Simulator

2.7 GLOVES

The gloves used in the restricted portions of the test (Conditions B and C) were size 9 3/4, .030" thick, "Neo-sol" gloves manufactured by the Charleston Rubber Co. of Charleston, S.C. The gloves were chosen because thay had the same characteristics as the "Buta-sol" gloves that were furnished with the Analog (Charleston Rubber Co. also manufactured the "Buta-sol" gloves).

The operator had only size 8 1/2 hands so the gloves were quite loose on him.

Cotton inserts were worn in the "Neo-sol" gloves to make them easier to get on and off and to reduce perspiration. The inserts were thin enough to have little effect on sensitivity of the operator's fingers - compared with the "Neo-sol" gloves without inserts.

2.8 DATA COLLECTED

Two types of data were taken:

- . Time for performance of each task.
- . Operator and observer comments.

The operator and observer comments provide valuable data for a qualitative measure of the severity of the working conditions and the operators reaction to these conditions. The times for performance of the tasks provide a quantitative measure of the relative difficulty of performing tasks under different conditions.

In order to permit the operator the maximum freedom in performance of the tasks, little effort was made to keep work methods constant in various situations. Instead, the main criteria was to accomplish the task in the most convenient manner, provided that certain restrictions were met. The restrictions were varied depending on the task. Because of the variations permitted, numerical data can only be considered as a relative indication of the time required to do a task. It cannot be considered accurate enough to be used to predict actual working times.

Most tasks were repeated twenty times for each condition. The purpose of this was twofold: (1) Non-representative factors could be eliminated from data and (2) The effects of learning would average out.

Comments on each task were recorded on tape during performance of the task. Afterward the tape was replayed and the principal comments were transcribed to a data sheet. This procedure had the advantage that comments were not lost because of failure to note them during performance. It was also found that considerable information could be gained by comparing the operator's tone of voice during different runs. His method of expressing himself and voice quality provided good indications of his mood during the tests.

3.0 TEST PROCEDURE

3.1 ORIENTATION

Prior to testing, the operator was given a brief orientation which defined the purpose of the tasks he was to perform. He was also shown the test plan and received an explanation of the concept of sterilization, work under sterile conditions, and the proposed Assembly/Sterilizer Facility.

In regard to the specific work involved, the operator was informed that it was not a time study and that the times taken would be used for comparative purposes only. He was asked to work at a normal rate and to try to maintain a constant level of effort throughout all tasks.

The operator was asked to try to finish each series of tasks without a break, However, he was told that if for any reason he felt it necessary to stop that he could and that he could rest until he was ready to continue working. This rule was followed throughout the complete series of tasks.

3.2 DAILY PROCEDURE

The same procedure was used in performing all tasks, both restricted and unrestricted, as follows:

- All tools, fasteners, components, etc., were laid out and arranged in convenient positions by the operator.
- 2) The operator was allowed to make a 'dry run' if he wished.
- 3) At the signal "Go" from the observer, the operator began assembly.
- 4) When assembly was complete, the operator signalled by saying "Ready". The time for assembly was noted by the observer. The operator immediately began disassembly.
- 5) On completion of the disassembly, with all parts put back into the starting position, the operator again said, "Ready" and the time was noted.
- 6) If anything significant was observed during the trial, comments on it were recorded. If not, comments were held until the end of the run.

4.0 MANIPULATION TEST RESULTS AND CONCLUSIONS

The results of the manipulation tests are presented in table DII. This table lists and describes the tasks performed and provides the time ratios for performance of the tasks under the four conditions and pertinent comments on the task. Sample calculations are provided in Attachment I hereto to show the data reduction technique used to provide the time ratios for performance.

Based on the data in table DII, comparisons have been made between the several test conditions in terms of the effect of the conditions upon the operator and his performance. In these comparisons, condition A forms the baseline from which the other conditions are evaluated.

4.1 COMPARISONS OF CONDITION B WITH CONDITION A

In performing tasks under condition B, the efficiency of the operator was less than that in Condition A. The average times for tasks increased by a factor of 1.91 from condition A to Condition B. Some of the factors which caused this were:

- 1) Loss of sensitivity
- 2) Decrease in dexterity
- 3) Gloves slipping down on hands
- 4) Sleeves of gloves cuffing over hands
- 5) Obstructed detail vision because of the size of the gloves. Also, the black gloves gave poor contrast when working with black parts
- 6) Great difficulty in performing some simple tasks without using special grasping tools.
- 7) Sweating of hands. This was not a major problem unless the room temperature was above 70° or the task was difficult enough to frustrate the operator.
- 8) Fatigue of hands when performing delicate operations (for example, task 11).
- 9) Inability to pickup flat objects from the work surface.

4.2 COMPARISON OF CONDITION C WITH CONDITION B

Rather than comparing condition C directly to condition A, it is more instructive to make the comparison to condition B. This shows the effects of individual differences between conditions.

TABLE D-II SUMMARY OF MANIPULATION TEST RESULTS

						TES	TEST RESULTS		E: ON		
	H	TIME RATION FOR CONDITIONS (NOTE	ION FO	CONDI	TIONS	(NOTE a)			JAI: JIII: ITON		
		PH7	PHASE 1 &	7	PHASE	21	FASTENERS	COMPONENTS	OND	PHASE	
TASK	PHASE	A	В	ပ		TOOLS USED	USED	USED	o	1 & 2	PHASE 3
1.Assemble Bracket to Chassis	-	1.00	1.62	1.68	() () ()	3/4"socket & ratchet; 3/4" adjust- able wrench.	1/2" hex bolt & nut	bracket, chassis		No problems	
2.Assemble Bracket to Chassis	1.	1.00	2.48	5.24	9.6	3/32" Allen wrench; 1/4" socket & ratchet; parts tray; tweezers.	#6 screw; 3/32" Allen -head screw & nut.	bracket, chassis	۵	Highest times for Condition C.Operator could not see dropped nuts & had trouble retrieving them.	Highest times for condition D.
3.Assemble Bracket to G Chassis	н	1.00	2.44	1.97		#2 Phillips driver; 7/16" box-end wrench; parts tray.	1/4" screw, #2 Phillips head & nut.	bracket, chassis	ں م	No problems.	
4.Assemble Bracket to Chassis		1.00	1.00 1.78	2.19	1.05	1.05 #1 Phillips driver (3" shank); 3/16" socket(with sliding han- dle); tweezers; slim-nose pliers; parts tray.	#2-40 screw, #1 Phillips head, & hex nut.	bracket, chassis	ں م	Room warm (76°F) humid.Frequent rests (every 4 or 5 trials) Frustrated by tweezers-better results with pliers.	Lowest time for condition D.
5.Assemble Bracket to Chassis	-	1.00	1.00 1.94	2.06		3/4"socket & ratchet;3/4" open-end wrench	1/2" hex bolt 1/2" hex nut	brackeţ, chassis	ਚ	No problems.	

PHASE 3			ន ជ		
PHASE	No problems	Used deep- well socket as aid in starting nut.	Marked learning curve. Screw starters very helpful.	No problems.	No problems.
SEE NOLE: CONDILION: SBECIVI	Q	ч ю	ς Υ, β,	ack f g ct-	60
COMPONENTS USED	bracket, chassis	Hubbel Connector, Chassis	chassis, amphenol connector, signal light hubbel con- nector, relay, terminal block, fuse holder.	Chassis; "black boxes", two bendix connecting pins.	Chassis; Fuse holder.
FASTENERS	1/4" screw~ #2 Phillips head & 1/4" hex nut.	#8-32 Phillips head screws (3); #8 hex nuts (3).	#10-32 slothead screw; #8-32 slothead screw; #6-32 slot; head screw; #4-40 slothead screw; head screw; #4 hex nut.	None	None
TOOLS USED	#2Phillips driver (1%" shank)7/16" box-end wrench;parts tray.	#1 Phillips driver (1" shank);11/32" deep-well socket.	2" & 6" screw starters (slot head); ½" socket wrench; slim- nose pliers; 1½" blade screwdriver/ starter; 3"& 8" blade screwdriver;	None	11/16" open- end tappet wrench.
Q	2.54				2.14 1.08
O	2.60	2.56	3.72	1.35	2.14
В	3.06	*	*	*	* 1
A	1.00	1.00	1.00	1.00	1.00
PHASE	н	1	ri	1	, k- sis
TASK	6.Assemble Bracket to Chassis	7.Assemble Hubbel Con- nector to Chasis	8.Connect (5) Wires to (5) Other Components from Amphenol	9.Connect (2) Plugs from Chassis to Baroswitch Connectors	10.Assemble Fuse Holder, Gasket, Lock- nut, Fuse & Cap to Chassis

TASK	PHASE	A	. <u>8</u>	ပ	Q	TOOLS USED	FASTENERS USED	COMPONENTS	REE NOLE: CONDILIONE RECIVT	PHASE 1 & 2	PHASE 3
11.Assemble Relay to Chassis	1	1.00	1.05	1.27	1.19	5/16" socket & nut driver handle; slim- nose pliers; parts tray.	#6 hex nut (2)	Chassis;Relay	ಐ ಇ	Used tip of slim-nose plier to start nut on stud.	
12.Connect 10-pin Amphenol Plug into Socket.	г	1.00	1.00	1.28	3.92	None	None	Amphenol Connecting Pin.	50	No problems.	
13.Connect 10- pin Amphenol Plug into Socket.	1	1.00	* 1	1.86	3.84	None	None	Amphenol Connecting Pin.	•ਜ	No problems.	
14.Gather (5) Wires; Clamp; Assemble Clamp to Chassis.	-	1.00	ጎ ና 1	3.68	1.08	#1 Phillips driver; }" socket with ratchet; parts tray.	Cable Clamp; #8-32 screw screw & nut.	Wires from Amphenol connector; chassis	60	Condition C proved tire- some; operator had to keep chassis from sliding away. Could not apply good "leverage" to ratchet. Frequent rests.	
15.Make Complete Assembly (5) Cycles.		1.00	* 1	2.08	2.94	Tweezers; slim-nose pliers; nut driver & 5/16" deep-well socket; #1 Phillips driver; 11/16" tappet wrench; 10" adj. wrench; 3/32" Allen wrench;6**	#4,#6,#8,& \$10 screws	Amphenol Con- nector, terminal block, signal light, fuse holder, relay "black box",2 bendix connect- ing pins, chassis	. V	Operator had "sense of accomplishment" only (5) trials (due to test length) Max. length task. Very pronounced fearning curve. Problem finding enough room for all tools in working area.	nse Most t" Compl test. gth)
-* No test scheduled.	schedul	ed.				slot-head driver; 5"&2"slot-head sc starter; pts. tra	ver; 1 screw tray				

TASK		PHASE	A	m	O		TOOLS USED	FASTENERS	COMPONENTS	SEE NOI CONDILI SECIVI	PHASE PHASE	en
16.Assemble Printed Circuit Board to Bracket Test Sample	ole o mple.	7	1.00	1.82	1.65		#1 Phillips driver.	#6 Phillips- head screws; parts tray	Test sample base, circuit board.		Wrist became very tired as a result of torque required to tighten screws into plate nuts.	
17.Assemble (1) Bar to Bracket on Test Sample	ole (1) Sracket Sample	6	1.00	*	2,43		Cleco Tool; fixture; parts tray.	Cleco fasteners.	Bracket on test sample, bar	귝	Cleco tool operated with (1) hand on bench - required (2) hands in glove bóx simulator. Cleco tool used to simulate "pop" riveter.	
18.Assemble Rivet Bar to Bracket	ble & ar ket.	7	1.00	* '	1.84		"Pop" Riveter.	"Pop" rivets 3/32" dia.	Bar, Bracket	H	Sleeve of rivet slipped down on rivet shank. Bracket shifted while (2) hands used to operate riveter.	
19.Assemble Test Sample by: (1) Assembling bar to bracket & (2) installing circuit board.	ble mple ing bracket nstallin	2 ng	1.00	*	1.89	5.20	#1 Phillips screwdriver; Cleco tool; fixture; parts tray.	Cleco fasten- ers; #6 screws	Bar, bracket of test sample circuit board	E C	Less tiring than task #16-Placing Cleco fasteners afforded some "rest"	
20.Repeat of Task #4.	t of	ı	1.00	*	3,33		#1 Phillips driver socket with sliding bar handle; slim-nose pliers; parts	#2-40 screws, #1 Phillips- head; hex nut.	Bracket, Chassis.	ں م	Attempted to complete entire task without "breaks". Operator could not continue beyond (17) trials.	
21.Repeat Task #10.	t of 0.	H *	1.00 No test	1.00 -* 1.95 No test scheduled	1.95 eduled.		tray. 11/16" open-end tappet wrench.	None	Chassis, Fuse holder	50	No problems.	

Notes for Table D-II

a. Ratios reported are: Average time per task, Condition A, B, or C, or D.

Average time per task, Condition A.

Condition "A" - Unrestricted work on an open bench.

Condition "B" - Work on an open bench but wearing gloves.

Condition "C" - Work performed in the glove box simulator.

Condition "D" - Work performed in the A/S Analog.

- b. The chassis was positioned, bottom down, parallel to the operator's shoulders. The bracket was positioned on the inside of the chassis with the projecting portion of the bracket beneath the nut. In this position the operator could not see most of the chassis interior, including the nut, when he was working in the glove box simulator. The chassis position is illustrated in Figure D-5.
- c. For Condition C, the operator was permitted to rotate the chassis so that he could see most of the interior.
- d. The bracket was placed on the outside of the chassis with the projection extending over the lip of the chassis and the nut. Chassis position same as (a).
- e. The chassis was positioned on its side, parallel to the operator's shoulders with the work being done on the upward side. This position is illustrated in Figure D-1.Bracket position same as (b).
- f. Condition C was performed before Condition A.
- g. The chassis was positioned, bottom down, parallel to the operator's shoulders.
- h. The chassis was positioned perpendicular to the operator's shoulders for Conditions B and C.
- i. The chassis was positioned on its side, parallel to the operators shoulders with work being done on the upward side.
- j. No restrictions on moving work during trials.
- k. Test sample, positioned on Fixture.
- Specially constructed U-shaped brackets were used to simulate the Test Sample because not enough test samples were available. The brackets consisted of a flat surface on one inch legs. The surface was perforated with two parallel rows of holes to which bars from the Test Samples

were riveted. The brackets were elevated to give the same working height as will be encountered with the Test Sample positioned in its fixture.

m. The Test Sample was hand held to place crews and positioned in its fixture to insert Cleco Fasteners.

Performance of tasks under condition C was not found to be significantly more difficult than performance of the same tasks under condition B. The average work times for condition C were greater than those for condition B by a factor of 1.16 (or greater than condition A by a factor of 2.22) If task #2 is deleted from the comparison, the average times for conditions B and C are the same. Some of the factors which distinguished the work situation for condition C from that for condition B were:

- Poorer visibility, which, in some instances led to severe operator frustration
- 2) A little uneasiness because of limited mobility.
- 3) A feeling of being too far away from work because of panel front.
- 4) Arms becomming cramped because they pressed on the edge of the arm holes in the panel when working in positions about six inches off the glove box work surface on when reaching over the chassis to work on the back side.

4.3 COMPARISON OF CONDITION D WITH CONDITION C

Comparison of condition D with condition C shows the effects of the pressure environment and work surface of the Analog.

Performance of work under condition D was found to be significantly more difficult than performance of the same tasks under condition C. The average work times for condition D were greater than these for condition C by a factor of 1.36 (or greater than A by a factor of 3.48). Some of the factors which created noticeable differences between conditions C and D were:

- 1) The use of a grating tends to slow down work by imposing a "fear" of dropping small parts through the grating. This tendency is offset somewhat by the fact that the use of a grating provides a work surface which prevents tools and the work piece from sliding.
- 2) The fear of puncturing the gloves during actual sterile condition increases work time.
- 3) The gas pressure on the gloves causes them to cling to the operator's hands and therefore increases the pressure sensitivity of the operator's hands.
- * 4) The gas pressure on the gloves places a force on the operator's arms which tends to push them out of the chamber.
 - 5) There was less working area in the Analog than in the mock-up.
 - * A more detailed discussion of these points follows.

The presence of the grating introduced two factors: One physical and the other psychological. The grating provided a much rougher work surface than the "mock-up." In some cases the rougher surface allowed more pressure to be put on a part, while in other cases, it hindered free movement of the work. The work was also affected a great deal by the operator's apprehension about dropping parts through the grating and losing them. Extra care was very much in evidence when the operator handled parts small enough to slip through the grating.

A puncture of a glove during actual operation of the assembly sterilizer would have meant violation of sterility and the subsequent loss of the many hours of labor previously expended. This fear was particularly in evidence during the assembly portion of all the sterilization cycles. This shows up in test condition D of task number nineteen. In this particular case the operator had to apply axial force to a Phillips screw driver to tighten four screws in a fixture held in his other hand. If the screw driver slipped (which it often did) there was a very real possibility of it striking and puncturing the glove on the other hand (which did not occur).

As previously discussed, only one operator was used for all manipulation tests. Thus by the time the condition D manipulation test was performed, he had had considerable experience in the Analog. This additional familiarity put the operator much more at ease in the working situation than at the inception of testing. This was particularly evident in his conversation. His remarks indicated that he understood fully what the tests were measuring and his desire to assist by fully discussing any facet of the work he thought important.

The pressure differential across the gloves caused then to cling tightly to the operators hands and arms. This increased the pressure sensitivity of his hands, with respect to the unpressurized "mock-up", but it also placed a force upon his entire arm which affected co-ordination and freedom of movement and was tiring.

There was thirty-four percent less working area in the Assembly/ Sterilizer than in the mock-up because of protruding doors and flanges. This situation resulted in poor placement of tools. The placement often required placing one tool on top of another, which often increased tool retrieval time.

4.4 CONCLUSIONS ON MANIPULATION TESTS

1. A wide variety of assembly tasks can be accomplished by an operator working in the restrictions of the Analog and wearing fairly heavy gloves.

- 2. The operator became very agitated several times, even though he was a stable individual. This indicates that careful operator selection is necessary to do any extensive work under sterile conditions.
- 3. Gloves should fit the operator as well as possible. In addition, it would be helpful to provide some means of keeping the sleeves of the gloves from cuffing over the hands when doing close work in an unpressurized environment.
- 4. Perspiration is not a major problem provided the operator is not frustrated by the working conditions.
- 5. Working in the Analog is not much more of a problem than merely working with gloves as long as the operator can see his work.
- 6. The time to perform a task in the Analog takes consistently longer than unencumbered work on an open bench.
- 7. The percentage increase in the time required to perform a task is roughly an increasing function of the complexity of the task.
- 8. There are some apparent inconsistencies in the test results. For example, task 4 was performed in condition D in less than one-half the time required for condition C.

An example of the results of work under condition D to ascertain the relationship of the time patterns and tasks is aided by reference to table DIII. This table extracts information from table D-II and reorganizes the data in order of decreasing ration of time for condition D to time for condition C. This sheds light on the apparent inconsistencies in test results. It is seen that connector mating in condition D takes considerably longer than in condition C and that simple tasks with large hand tools take less time in condition D. It is further seen that if the task is of sufficient complexity, performance under condition D takes more time than under condition C. Thus observable patterns exist.

It is also seen from table D-III that as a task becomes quite complex the data tends to stabilize. Task 15 is the most complex task performed and has a D/C time ratio of 1.41; the average of all the tasks gives a D/C time ratio of 1.36. Thus a sufficiently complex single task is representative of the average of the entire experiment as far as comparing condition C and D is concerned.

TABLE D-III

TEST RESULT COMPARISONS

Ratio of For Cond	ditions	Task <u>Number</u>	Tools Employed
D/C	D/A		
3.06	3.92	12	None - 10 - pin connector mating.
2.75	5.20	19	<pre>#1 Phillips screwdriver, Cleco tool</pre>
2.06	3.84	13	None - 10 pin connector
1.83	9.6	2	3/32" Allen wrench, 1/4" Socket & Ratchet, tweezers
1.41	2.94	1 5	Wide range of tools (see table D-II)
.98	2.54	6	#2 Phillips screwdriver, 7/16" box end wrench
.94	1.19	11	5/16" Socket with nut driver, slim nose pliers.
.50	1.08	10	11/16" Open end tappet wrench
.29	1.05	14	<pre>#1 Phillips screwdriver, 1/4" Socket and ratchet</pre>
1.36		Average of tasks	All the Above tools

5.0 TOOL STERILITY STUDY

5.1 STERILIZATION OF TOOLS

Most tools will not withstand sterilization by dry heating or steam autoclaving. This was determined by subjecting several tools - screwdrivers and pop riveters - to sterilization cycles. The following problems were encountered:

- Screwdriver Plastic handle became soft at 250°F. Melted at 300°F. A nickel-steel shank rusted badly when autoclaved at 250°F.
- . Pop Riveter Moving parts galled when degreased. However, the materials withstood 300°F heat sterilization. The riveter was not autoclaved.

Since most tools are made of materials similar to those in the screwdriver and pop riveter, it is evident that care must be exercised in selecting tools for sterilization work. The problems that must be avoided are:

- . Melting Plastic and rubber handled tools
- . Rusting Most common metal tools
- . Galling Tools with moving parts

Several manufacturers do make lines of tools that will probably withstand the sterilization cycles. Two of them are:

- . Snap-on Tools, Incorporated of Kenosha, Wisconsin
- . Beryllium Corporation of Reading, Pennsylvania

Snap-on offers a special line of clean room tools that are treated by a process called electroless plating. Although not specifically made for sterile work, Snap-on representatives felt they would probably work. (None were tested because the tools are fabricated to order and the waiting period was too long to get a sample tool before completion of the tests.)

The Beryllium Corporation manufactures a standard line of beryllium-copper alloy tools (98% copper - 2% beryllium). A screwdriver shank of this material was subjected to 3 one hour autoclave cycles with no ill effects except a thin oxide coating which is not considered harmful.

Surgical steel tools are of an acceptable quality for sterile work. However, the tools are so specialized that very few can have any value for assembly work. Two catalogues were reviewed - a surgical catalogue and a dental catalogue - and only about five tools showed any promise except for very special applications.

No manufacturer of acceptable handles was found. All handles surveyed were either thermo-plastic or wood. Plastic is not acceptable for the reasons given above. Wood was not tested because advice was received that wooden frames heated to 300°F during cure cycles deteriorated and burst into flame when exposed to air. However, an experienced machinist was able to fabricate an aluminum handle and attach it to a copper-beryllium shank in twenty minutes, so this problem is not insurmountable. The aluminum handle was also subjected to 3 one hour autoclave cycles with no adverse effects other than a thin oxide coating. A further consideration would be to manufacture molded handles of high temperature plastics, many of which are available.

The problem of moving parts galling must be resolved by either obtaining tools of non-galling materials or with sufficient tolerance that galling is not a problem if the tools are to be operated without lubrication. If the tool is lubricated, either silicone or teflon lubricants appear to be good possibilities.

The problem of the pop rivet tool galling was resolved by machining parts to increase tolerances. Prior to this, use of a lubricant was considered. However, no further study of lubricants was made because it was not necessary to continue the tests and was outside the scope of the Test Plan.

5.2 RESULTS AND CONCLUSIONS - STERILIZABLE TOOL STUDY

Conclusions on types of tools suitable for sterile assembly procedures were drawn during the tests described above.

In general, all the tools tested worked well while wearing gloves. Some would work with slight modification. The major difficulty, however is in finding tools that will withstand the sterilization and decontamination cycles. Two manufacturers were found who produce tools of materials that appear to be generally compatible with sterilization work. Most tools require only a change of material to be suitable for sterilization.

Several tools were found very helpful in handling small screws. The main ones were Phillips Head and Slot Head screw starters. These were of considerable assistance in handling #8 screws and smaller which are very difficult to handle without some pickup tool. Screw starters in two and five inch lengths were used. All worked well, except that the starters tended to pop out of the screw head if the operator wasn't careful in handling them. This was especially true when handling Phillips Head screws.

A magnetic pick-up tool also worked well. This would be very helpful in situations where it could be used without adversely affecting hardware.

A tool that would be very helpful in handling nuts is a "grip-tite" manufactured by the Walden-Stevens Corporation. None were available in the plant so they were not tested. (It was not known that such as tool existed until it was too late to order one.) However, these would be of considerable help in picking up and starting nuts of various sizes.

All of the tools listed in table DI except the tweezers could be used with little difficulty while wearing gloves. The following list shows tools which gave some problems.

. Tweezers

The handle was too small to work easily with thumb and fingers.

The tip came to a point rather than a flat surface so that nuts tended to spin when held with the tweezers. The tweezers could be used but it was very frustrating - especially on fine work.

. Slim Nosed Pliers

It was difficult to insert a finger between the handles to open the pliers. Otherwise, they worked very well. A spring to force the pliers open would help.

. Ratchet

The eighth inch high knob used to reverse the ratchet was too low. A quarter inch knob would work well.

Screwdriver with Spring Screw Holder

The spring was difficult to operate while wearing gloves.

. Pop Rivet Tools

Two pop riveters were used. With both it was necessary to use both hands to open the handle wide enough that the pop rivets could be gripped by the collet.

. Tongs

The finger holes were too small to allow fingers to be inserted into them easily while wearing gloves.

APPENDIX D ATTACHMENT I

SAMPLE CALCULATIONS

The following is an example of calculations for a typical set of data. Calculations were very simple. Data from which atypical results had been deleted was averaged to get a mean time for performance of the task for Conditions A, B and C. The ratio of the means for Conditions B and C to Condition A was then calculated to get the ratios reported in Table D-II Overall ratios were calculated by averaging the ratios for all tasks.

Calculations for Task 2 are shown:

Time in minutes for assembly and disassembly for Condition:

		<u>A</u>	<u>B</u>	<u>C</u>
Trial	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	.44 .51 .39 .37 .31 .35 .32 .36 .32 .32	.87 .82 .65 1.17 .92 .71 .63 .64 .60 .75 1.21 .68 .76 .68 1.05 .66 .89 1.23 1.29	* .62 .73 .65 .83 .72 .85 .65 .70 .71 .68 .58 .64* .65 .74 .80 .92
	20		1.52	.68
Sum		4.0	1 7.73	12.15
Mean		.36	.88	.71
Ratio t	o A	1.00	2.44	1.97

Sample calculation of mean:

Mean A =
$$\frac{4.00}{11}$$
 = .36

Sample calculation of ratio:

Ratio (B:A) =
$$\frac{.88}{.36}$$
 = 2.44

Footnote:

* = Rejected Data.

** = Trials were stopped because there were few problems and data was relatively consistent.

APPENDIX E: PRELIMINARY FULL SCALE DESIGN STUDY

1. SUMMARY

A. INTRODUCTION

As part of the work statement performed under NASA contract NAS 1-5381*, the General Electric Company, Re-entry Systems Department, has performed a preliminary design study of a full scale Assembly/Sterilizer facility. This report presents the results of the study.

The design study was restricted to a preliminary design for two primary reasons. First, the status of interplanetary programs at start of the study dictated that any design be based more on assumption than on detailed definition of the actual interplanetary vehicle systems to be supported. Second, until the feasibility of the Assembly/Sterilizer has been demonstrated, NASA could not reasonably commit the funding necessary to permit a more definitive design of the facility.

The program of which this study was a part has demonstrated the feasibility of the Assembly/Sterilizer concept, and the preliminary design study has resolved the major questions about the practicability of constructing a facility to implement the concept.

B. OBJECTIVES OF STUDY

The basic objective of the study was the investigation of the feasibility of construction of a full scale Assembly/Sterilizer through the performance of a preliminary design exercise. This objective formed the basis for the definition of several subtasks for the study. These are:

- a) Define Assembly/Sterilizer facility design ground rules. (These in essence constitute an informal first draft of an Assembly/Sterilizer System Specification)
- b) Identify and describe facility concepts compatible with (a).
- c) Identify probable construction materials and techniques.
- d) Perform design analyses as required to establish feasibility of facility.
- e) Identify facility design problems.
- f) Identify potential solutions to design problems
- g) Estimate cost and schedule for detailed design and construction of a full scale Assembly/Sterilizer facility.

^{*} NASA Contract NAS 1-5381 - A Research Program to Demonstrate the Feasibility of an Assembly Facility, 21 July 1965.

Particular attention has been given to the layout and structural considerations for the Assembly/Sterilizer. Unique problems arise due to the material flow considerations and the requirement for large hermetically sealed dry heat sterilizing chambers with Class 100 clean room capability.

C. STUDY GROUND RULES

The study ground rules were defined at the initiation of the study and amended as the study progressed to reflect the latest thinking. These ground rules defined the study scope, study objectives, and the facility design ground rules. For a more logical presentation in this report, these three topics have been covered independently in A above and 2A and B below.

D. CONCLUSIONS

The study has given preliminary indication of the feasibility of the construction of an Assembly/Sterilizer facility. In particular, the major design and construction problem, structural design of the Assembly/Sterilizer portion of the facility, has been resolved. Based on the investigation of this problem, it can be concluded that construction of a practical Assembly/Sterilizer facility is possible within the realm of engineering, materials, and construction methods presently available.

Complete resolution of the next most important problem, thermal control, has not been made. The thermal control problem has been quantified in the study and the approach to its resolution identified. Additional analyses are needed to evaluate the approach. Specifically, the areas that require investigation are the sizing and design of heat exchanges for the back loop of the recirculating gas systems and sizing and control of plate coil wall skin sections.

No effort has been concentrated on general control instruments, gas supply plumbing or other aspects of the facility which in essence reduce to the application of proven conventional equipment and techniques to the Assembly/Sterilizer facility.

The feasibility of the Bio-Isolator Suit System (BISS) is central to the final decision on the feasibility of the A/S. Investigation of BISS was beyond the scope of the present study, but is being covered by G.E. under NASA contract NAS1-6537.* The results of BISS investigation to date are very encouraging, and no obstacle to the realization of a fully satisfacting BISS system is foreseen.

Experience with the Assembly/Sterilizer Analog during the program has shown that the concept of a full scale facility can be implemented on a much reduced scale. Further, independent studies by G.E. have investigated the problems associated with design and construction of a room size prototype of the Assembly/Sterilizer. This study has indicated that such a facility prototype is practicable. This experience with the Analog and the investigation of a prototype reinforces the over-all conclusion that the full scale Assembly/Sterilizer is feasible.

^{*}NASA Contract NAS1-6537 - A Research Study to Definitize a Bio-Isalator Suit System (BISS).

2. FACILITY CONCEPTS

A. SCOPE OF FACILITY STUDY

Particular attention is given in the study to the Assembly/Sterilizer Chamber and its auxiliary chambers because these chambers present the unique design and construction problems. The basic problem centers on handling different gases and maintaining Class 100 laminar flow clean room conditions in hermetically sealed chambers over a range of elevated temperatures and at a restricted limit of positive pressure.

The primary chambers of the Assembly/Sterilizer consist of the following:

Assembly/Sterilizer Main Chamber - Used for sterilizing subsystems and complete space vehicles with subsequent checkout, repair, and assembly in a sterile environment.

Assembly/Sterilizer Vestibule - Used as a decontaminating sterilizing pass-through to the main chamber.

Pyro Oven - Used for sterilizing the rocket motors and stress pyrotechnics prior to their introduction to the main chamber for sterile insertion in the space vehicle.

To properly support the function of the Assembly/Sterilizer Chamber, various laboratories, repair shops, personnel preparation areas, passthroughs, and service areas are required. These areas, although presenting no unique design problems must be appropriately related to the sterilization/assembly facility. The chambers and the support areas must be studied in the context of the total facility system.

B. ASSEMBLY/STERILIZER FACILITY DESIGN GROUND RULES

1) PURPOSE

The A/S is intended to permit the decontamination and sterilization of a partially assembled interplanetary spacecraft lander; with subsequent sterile checkout, adjustment, and repair; and sterile insertion of vehicle equipment or scientific experiments. The full facility incorporates the A/S plus required supporting and service areas.

2) VEHICLE

The vehicle to be processed in the facility shall be up to 20 feet in diameter and up to 20 feet long. Vehicle designs up to 10,000 pounds shall be considered. In addition to the vehicle, a biological barrier shall be processed in the facility.

3) MATERIAL FLOW

The basic flow for the material in the facility is shown in figure E-1. The material is received from the factory, uncrated, and stored in the Receiving and Incoming Storage area. When ready for transfer to the clean-room, the equipment is processed through a cleaning area. Subsequent in-flow transfers are made in controlled corridors or through direct pass-throughs from one area to the next. Equipment will not normally flow from a clean (or sterile) area to a less clean (or contaminated) area unless it is protected against recontamination by a barrier.

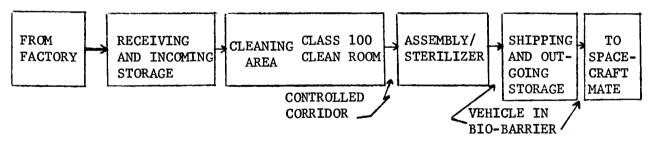


FIGURE E-1 BASIC MATERIAL FLOW IN A/S FACILITY.

The flow of materials in the Assembly/Sterilizer is described in attachment 1 to this appendix.

4) SITING

For the purposes of this study the A/S facility has been assumed to be located at the Air Force Eastern Test Range (AFETR) at Cape Kennedy, Florida. The building has been considered as a new construction and

it was further assumed that a building location and access roads would be provided compatible with the functional and safety requirements of facility design. To aid in the proper reflection of the site requirements in the study, the following references have been employed.

- a. "Statement of Work and Specifications for Engineering, Furnishing and Installation of a Vertical Laminar Flow Clean Room." Lunar Orbiter Project, Explosive Safe Complex, Area 5/6, Cape Kennedy. Unmanned Launch Operations Directorate, Kennedy Space Center, January 12, 1966.
- b. KSC Operating Plan, Apollo/Saturn V Program, Appendix E, Systems

 Descriptions. Revision 2, dated November 1, 1964 (Preliminary).

 Prepared by General Electric Company, Apollo Support Department,

 KSC Checkout Engineering, Cape Kennedy.
- c. Apollo/Saturn V, MILA (Merritt Island Launch Area) Facilities

 Descriptions. K-V-011, Coordination Draft, dated June 30, 1965.

5) UTILITIES

All required utilities have been assumed available at the building site in the form and quantity required. Part of the study output is the definition of Utility requirements.

6) CONTROLLED ENVIRONMENT MODES

The main chamber vestibule, and pyrotechnic oven shall have four basic environment modes.

a. Maintenance and Transfer - AIR

- *. Class 100 vertical laminar flow of 90 + 15 fpm
 - . Atmospheric air
 - . Temperature of $75 + 5^{\circ}F$
 - . RH less than 90%
 - . Pressu: ambient
 - . Duration indefinite

b. Decontamination - ETO/FREON

- *. Class 100 vertical laminar flow of 90 \pm 15 fpm
 - . ETO/FREON (12%/88% W/W) concentration of 400 mg/later of ETO nominal, decreasing as an inverse function of absolute temperature above $130^{\circ}F$.

- . Temperature of 70 to 150°F
- . RH of 50 to 60%
- . Pressure up to 4" H2O gage
- . Duration up to 24 hours

c. Sterilization - Nitrogen

- *. Class 100 vertical laminar flow of 90 + 15 fpm
 - . Nitrogen
 - . Temperature of 105 to $160^{\circ}\mathrm{C}$, the standard time/temperature treatments are tabulated below.

Temp (°C/°F)	Duration (Hr)**
160/320	3
155/311	4
150/302	6
145/293	9
140/284	14
135/275	22
130/266	34
125/257	53
120/248	84
115/239	132
110/230	210
105/221	336

- . RH less than 1% above 200°F
- . Pressure up to 4" H20 gage
- . Duration as tabulated above plus temperature transition times.

d. Working - Nitrogen

- *. Class 100 vertical laminar flow of 90 + 15 fpm
 - . Nitrogen
 - . Temperature of $75 + 5^{\circ}$ (controllable + 10%)
 - . RH of 20 50%
 - . Pressure up to 4" H20 gage
 - . Duration indefinite

For this study, a nominal maximum temperature of $+300^{\circ}$ F was assumed.

^{*} Subject to revision based on further considerations of the need for laminar flow in the Assembly/Sterilizer facility (see Section).

^{**} Time after equipment reaches thermal equilibrium. Total time includes rise and decay times for chamber and equipment also.

C. SITE CONSIDERATIONS

- 1) The site selected for the Assembly/Sterilizer is the AFETR at Kennedy Space Center. This selection is based on consideration of pre-launch activities in a normal flight program. Experience from such programs indicates the desirability of controlled access to the flight vehicle as late in the pre-launch period as possible. Thus, sterilization should be performed as late as possible consistent with total pre-launch activities schedules. Of particular importance also, is that the significant advantages to be gained by the re-cycle repair capability of the Assembly/Sterilizer Analog can be fully realized only if the facility is located at the launch base.
- 2) At Kennedy Space Center (KSC) and Merritt Island Launch Area (MTLA), the reported high water table makes it impractical to use a facility configuration requiring substantial excavation for basement areas. Conversations with KSC Facilities Engineering personnel indicated that excavations in excess of 10 feet would be unusual in that vicinity.
- 3) The relation of the Assembly/Sterilizer Facility main operating floor to the ground datum line affects the overall height of the structure above-grade and to some degree the cost of constructing the facility. The configurations studied can be seen in various relationships to the ground line. Any final decision on the above-grade vs. belowgrade instruction must trade off cost vs. construction and operational complexity for the alternatives.

D. MATERIALS HANDLING

The normal problems of materials handling are complicated in the Assembly/ Sterilizer facility by the requirement to maintain bio-cleanliness or absolute sterility in parts of the facility. It is expected therefore that all handling jigs, fixtures, etc. may have to be of special design.

Materials handling was not investigated in depth in this study, however, consideration was given to the problem to the extent that it biases the design of the facility.

1) DOLLIES

Equipment assemblages up to 20 feet in diameter and 20 feet long and weighing up to 10,000 pounds must be worked on and moved through the facility. Dollies to move such large assemblages will require special design because they must not only support and transport the equipment but they must be able to withstand the environments of the Assembly/ Sterilizer main chamber.

The size and weight considerations suggest several design constraints.

- . Positive directional control (e.g. no rubber tired casters)
- . Self contained motive power
- . Multiple control locations (i.e. either end and possibly either side)
- Easily actuated brakes

To achieve positive directional control in a dolly composed of materials able to withstand 300°F it may be desirable to use steel wheels running in fixed wide gauge tracks. Such a scheme would also reduce the effort required to move the loaded dolly over that which would be required for a rubber tired dolly. However, these advantages are gained at the expense of flexibility of floor space utilization. If steel wheels were to be used, they would be freely pivoted with a slight caster. Catches would be provided to permit locking the pivots in position. To prevent the need for wide radius turns or large turntables, small turntables could be used as shown in Figure E-1A.

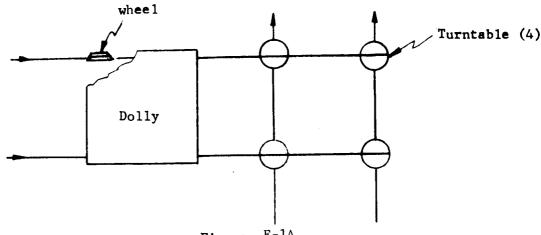


Figure E-1A
Dolly Turn-Table Configuration

Self contained motive power can be achieved by using battery powered electric motors. If such a scheme is used however, it will be necessary to have the batteries on a separable cart which is a part of the dolly so that batteries need not be exposed to the 300°F temperature. Subsequent movement of the dolly in the main chamber after sterilization could be achieved by running a power cable to the dolly, or the dolly could be moved manually as is common practice with steel wheeled vehicles (boxcars) in industry.

Multiple control locations can be achieved by using a plug-in electrical control set with receptacles at several places on the dolly.

The brakes should probably be electrically actuated with back-up mechanical actuation for "parking".

2) SUPPORT STANDS OR FIXTURES

The primary question for support stands and fixtures is whether the vehicle and its sections attached thereto should have their centerlines horizontal or vertical (see Figure E-2). A comparison of some effects of these two alternatives is given in Table E-1.

TABLE E-1

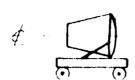
EFFECTS OF HORIZONTAL & VERTICAL POSITIONING OF VEHICLE SECTIONS* ON STANDARDS OR FIXTURES

	PARAMETER	HORIZONTAL	VERTICAL	MOST DESIRABLE
1	Laminar air flow disturbance	Least	Greatest	Horizontal
2	Efficiency of heat transfer from air stream to equipment	Least	Greatest	Vertical
3	Technician access to inside of vehicle section	Greatest	Least	Horizontal
4	Bio-confidence	Greatest	Least	Horizontal
5	Stand complexity and weight	Greatest	Least	Vertical
6	Ease of Mating	Least	Greatest	Vertica1
7	Headroom required	Least	Greatest	Vertical

^{*} The vehicle sections are assumed truncated cones closed on one end.

HORIZONTAL

VERTICAL



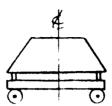


Figure E-2

Vehicle Section Position Definition

Each of these relative decisions should be rather apparent with the distinct exception of the bio-confidence. The laminar air flow disturbance will be a function of the area projected normal to the air flow. For a truncated cone this will be greatest in the vertical position. Likewise the efficiency of heat transfer should also be a function of projected area, thus being greatest for vertical.

In indicating that the technician access is greatest for the horizontal center line, there is an unstated assumption that the fixture permits rotation of the vehicle section about its centerline. This assumption assures, that the complexity and weight of the horizontal fixture will be greatest.

The ease of mating should be clearly seen to be greatest with the vertical positioning. Horizontal mating, in addition to being more difficult, requires at least 3 axis motion of the fixture. However, the vertical mating requires an overhead crane (bridge crane or dolly crane) which the horizontal does not and it also requires higher ceiling heights. Although overhead cranes will probably be required in some sections of the building to facilitate crating and uncrating and placement of vehicle sections on dollies, stands, or fixtures, the problems inherent in using an overhead crane in a vertical laminar flow clean room or a sterile chamber are quite different from those associated with the use of cranes in conventional areas.

The bio-confidence compatison results from considering that the suited operator who must climb up on top of or under a vehicle section, as would probably be necessary with vertical positioning, would be much more apt to puncture or rupture his suit. Further, any contamination that might result from such a break in the BISS suit would more likely sweep into the equipment if the man is above the vehicle section than if he is along side the section.

These considerations were reviewed with the NASA/LRC technical representatives and the decision was made to restrict the subsequent study efforts to horizontal handling in the clean room and the Assembly/ Sterilizer chambers. The most dramatic single effect of this decision is reduction of the required head room in the clean room and Assembly/ Sterilizer main chamber with a consequent reduction in building height.

Using horizontal positioning, a clear interior height of 30 feet between floor and ceiling is considered satisfactory for the Assembly/Sterilizer chamber and Class 100 clean room. Handling, movement, and mating of hardware and assemblies will be by means of dollies and movable fixtures. No overhead cranes will be required in these chambers. Vertical assembly mating would require clear working headroom of 48 feet. A previous facility study ("Voyager Capsule Pre-Proposal Facility Study" November 1965, prepared for GE Re-entry Systems Department by Jackson & Moreland, Boston, Mass.) for final assembly and test of Voyager Capsules also showed 30 feet as the clear ceiling height in assembly areas.

In addition to reducing the volume of the required work spaces, vertical positioning results in corresponding reductions in the size of the gas handling systems, quantities of special gases, operating costs, and initial cost of the facility.

E. BUILDING LAYOUT

In order to make a meaningful design study of the Assembly/Sterilizer, it was necessary to incorporate it in a building comprising, with the Assembly/Sterilizer, the full scale Assembly/Sterilizer facility. This necessity results from two facts: (1) In order to establish the feasibility of the Assembly/Sterilizer, it must be shown that it is capable of incorporation into a full facility which will permit practical, efficient, safe, controlled processing of the flight hardware, and (2) the Assembly/Sterilizer design and some aspects of the building layout are so closely interrelated that they must be studied together.

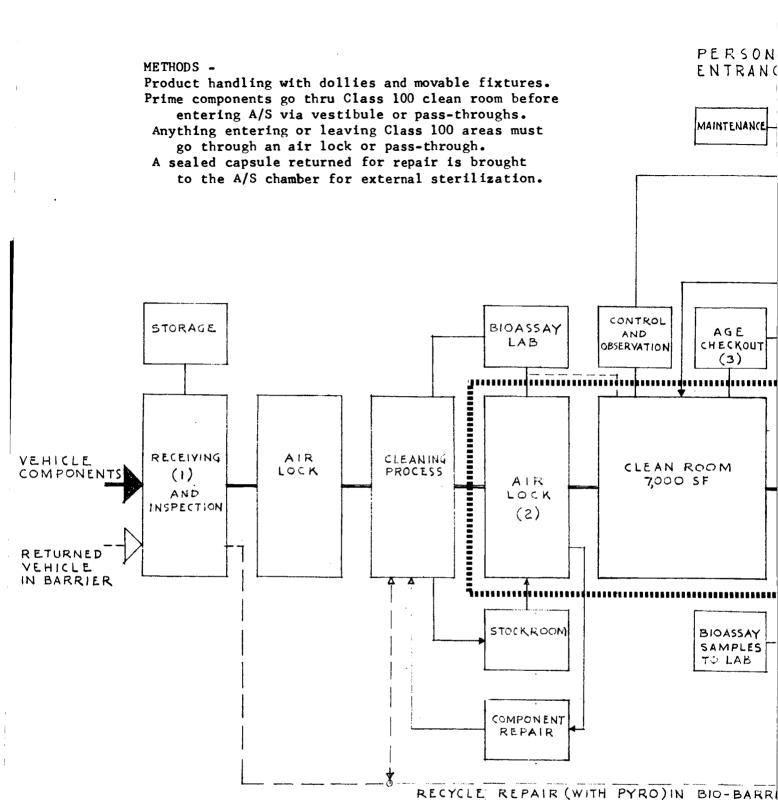
This second point should become clear in the following discussion; however, for the moment, consider the structural interface between Assembly/Sterilizer and building, or the relationship between placement of support areas outside the Assembly/Sterilizer and the location and design of provisions for access to the Assembly/Sterilizer main chamber.

1) LAYOUT CRITERIA

Some of the criteria which have governed the present layouts of the Assembly/Sterilizer facility building are summarized below.

- In tracing the flow of material through the facility, there should be a minimum of doubling back or recrossing a previous flow path.

 (Basic material/personnel flow is presented in Figures E-3 and E-4.)
- Emphasis on maintenance of bio-cleanliness of hardware should be in direct proportion to the size and complexity of the hardware item. (It is much easier to re-clean a component which has been removed from the clean room for repair than it is to re-clean a full vehicle section).
- . Crossing of personnel and material flow paths should be minimized.
- . The layout shall permit, to the maximum extent possible, flow of material on one level. Bio-clean areas shall be restricted to one building level to eliminate the problems of trying to maintain bio-clean stair towers and elevators.
- Repair shops will not be bio-clean. Repaired items will be cleaned before reintroduction to prime material flow.
- No major machine shops will be required for flight hardware maintenance. Major: metal rework will be performed outside the facility. (If this ground rule is subsequently amended, the building layouts have adequately undeveloped floor space to permit incorporation of additional repair shops.)
- Bio-assay labs shall be located with at least one wall common to the clean room to permit pass-through of assay samples from the work floor. The assay lab shall be also convenient to the A/S main chamber. Assay sampling in the clean room shall be done by personnel in the clean room who do not enter the lab. Assay in the A/S main chamber will probably be done only when the chamber is shut down or operating as a vertical laminar flow



NOTES:

EV Explosion Vented

* Pass-thru chambers

Class 100 areas

(1) Shipping and receiving may be adjacent

(2) Could be same air lock if feasible

(3) Common area and equipment if possible

(4) Separate receiving area if hazard warrants

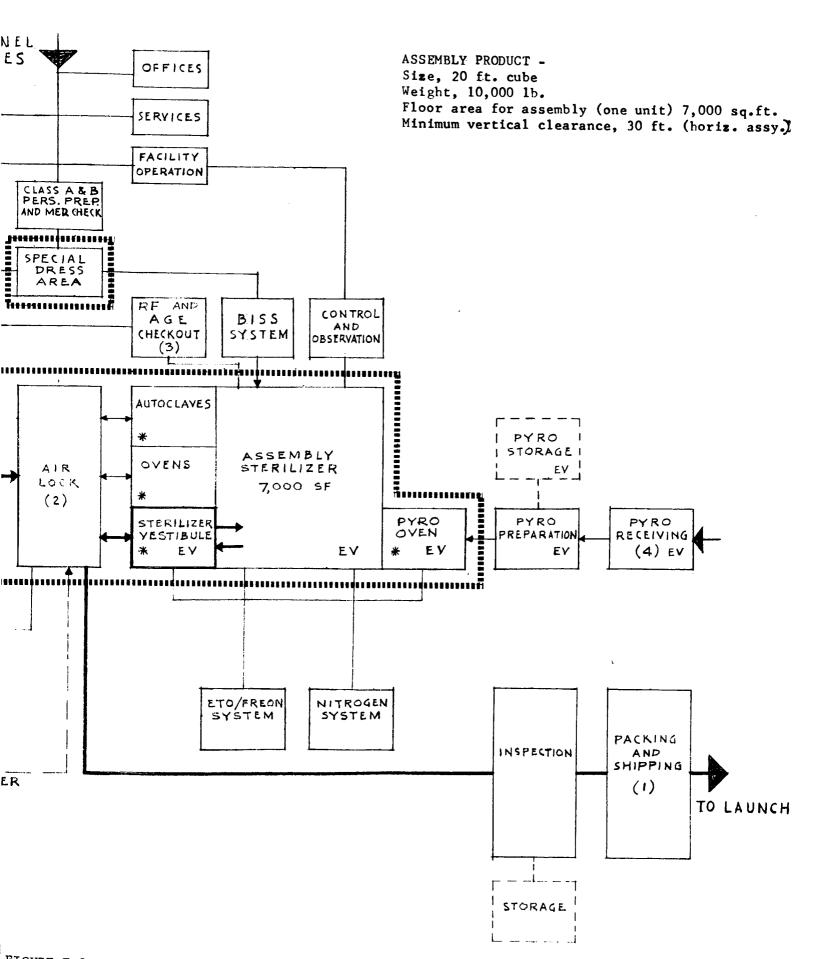


FIGURE E-3 ASSEMBLY/STERILIZER FACILITY
BLOCK DIAGRAM AND FUNCTIONAL RELATIONSHIPS

clean-room with an air atmosphere. Assay personnel would then enter the main chamber through the vestibule. If subsequent studies demonstrate that it is desirable to assay the sterile main chamber routinely, the assay sampling could be done by BISS suited technicians.

- Direct access to the long sides of the main chamber is required to permit BISS personnel to enter their suits.
- . Direct access to the main chamber wall is required for the pass-through area.
- RF equipment for vehicle systems' checkout in the main chamber shall be located in a room on one wall of the main chamber to minimize test cable lengths from vehicle to test equipment. Other AGE equipment may be located remotely.
- The Assembly/Sterilizer control stations and observation areas shall have a view of the full Assembly/Sterilizer main chamber floor and at least TV coverage of other Assembly/Sterilizer locations.
- An emergency room(s) shall be located as close as possible to the BISS personnel for treatment of BISS workers in event of illness or injury.
- The pyrotechnic preparation area and pyro oven shall be located as far as possible from personnel flows and radiating RF equipment. The pyro area and oven shall have explosion relief to the outside wall of the building. Pyros shall be handled separate from other material except when the pyros are installed in the vehicle. Pyros shall be sterilized separate from the vehicle. Provisions for explosion relief in the Assembly/Sterilizer main chamber shall be considered.
- . The vestibule ducting shall have explosion relief provisions to channel to the outside any possible explosion due to sterilization of a biobarrier encased, fully assembled vehicle being returned to the sterile Assembly/Sterilizer main chamber for repair.
- . It shall be possible to bring a complete returned vehicle into the Assembly/Sterilizer vestibule for sterilization of the bio-barrier, without entering the clean room or Assembly/Sterilizer main chamber.
- . Provision shall be made to move equipment from each level to the shipping and receiving areas (elevators).
- . The basic grid for building layout shall be 24 feet. The ceiling heights shall be in multiples of 4 feet (12, 24, and 48 actually used in the accompanying floor plans). Modified grids may be used for the Assembly/Sterilizer chambers and clean room where necessary.

2) PERSONNEL

In general the operational requirements of the Assembly/Sterilizer Facility will determine the types and number of personnel needed. The various categories of personnel and their work areas are shown schematically in Figure E-4, Personnel - Types, Processing and Services.

Four classes of personnel are identified in figure E-4: Class A - Bio-clean Personnel, Class B - BISS suit personnel, Class C - Bio-lab personnel, and Class D - Uncontrolled personnel. In general, these four classes are required regardless of building layout. However, the specific restrictions and details of flow for each class may vary somewhat with the specific building layout under consideration. The personnel classification descriptions for building plan A (shown in figures E-7 and E-8 following) are presented here to give an illustrative example.

In plan A the personnel flow is primarily on one level. (A second lobby would be added in the office area for office and sterility control personnel entrance).

The personnel classes for plan A are:

Class A - Bio-clean Personnel

These personnel include assembly and checkout personnel and bio-technicians who work in the Class 100 clean-room. Class A personnel dress in a special preparation area after doffing street clothes in an outer locker room, showering, and being subjected to a physical examination intended to eliminate from the work crew on any given shift personnel who are potential sources of extraordinary amounts of biological contamination in the clean room due to colds, open sores, etc.

Personnel working in the Assembly/Sterilizer pass-through area will prepare with Class A personnel and then proceed to their work area along the outside corridor.

All Class A personnel are male.

Class B - BISS Suit Personnel

These personnel work in the suits of the Assembly/Sterilizer BISS (Bio-Isolator Suit System). Class B personnel dress in a special preparation area after doffing street clothes in an outer locker room, showering and being subjected to a physical examination intended to assure that their health is such that they will not suffer from the rigors of BISS work and that they do not have infectious or contageous diseases or ailments which will adversely affect other personnel who will work in the same suit.

Class B will wear special undersuits and will be required to use body deodorants. These personnel will proceed to their work areas by way of corridors.

All Class B personnel are male.

Class C - Bio-Lab Personnel_

These personnel work in the Bio-Assay Laboratory. Class C personnel dress in the Class B preparation area after doffing street clothes in an outer locker room. These personnel are not required to undergo medical examination or showering before dressing. These personnel will proceed to their work areas through corridors.

Class D - Uncontrolled Personnel

These personnel have assignments which do not require any special control of clothing, health, or personal hygiene. Class D personnel work in the ofices, Assembly/Sterilizer control station, repair shop, AGE areas, shipping and receiving, and in building and facility maintenance.

The restriction of Classes A, B and C to the male personnel is for the purpose of reducing preparation area requirements and personnel flow problems. If female personnel are added, additional preparation areas must be added with provisions to get these personnel to and from their work areas.

Personnel classification descriptions for other building layouts would be materially the same as these.

Until the various operating procedures the facility can only be estimated. For planning and design purposes, assumptions were made regarding the number of facility occupants. Table E-2 identifies the work areas and shows the estimated number of personnel in each.

TABLE E-2 ESTIMATED NUMBER OF ASSEMBLY/STERILIZER FACILITY PERSONNEL

AREA		OCCUPANTS
Clean Room		30
BISS (suit and support pers	sonne1)	20
Support Areas		35
Shipping and Receiving Bioassay Lab Pyro Areas Component Repair	3 10 3 5	

AREA		OCCUPANTS
Stockroom 1 Precleaning Area 4 AGE 9 35		
Monitoring and Control		10
Maintenance Areas		5
Office Area		25
	TOTAL	125

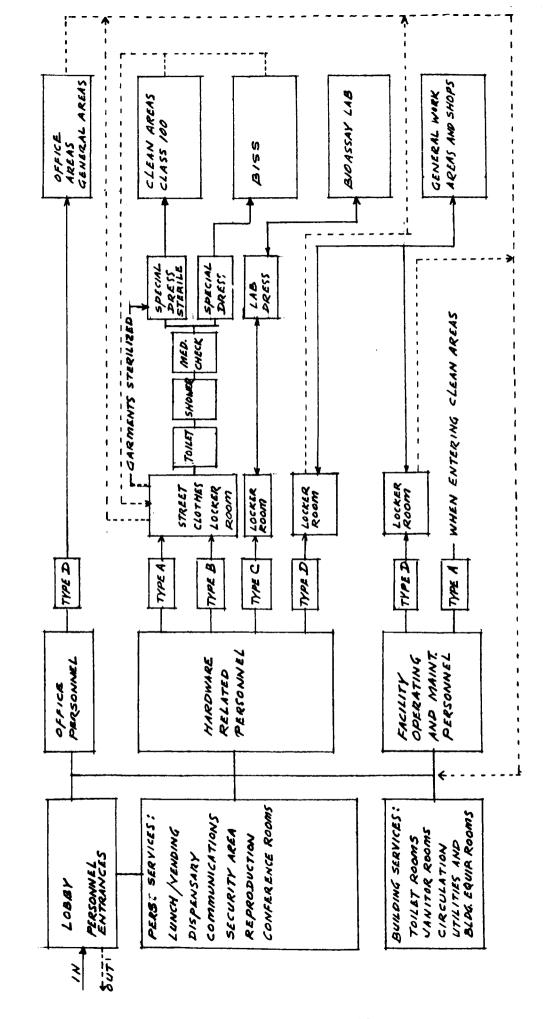
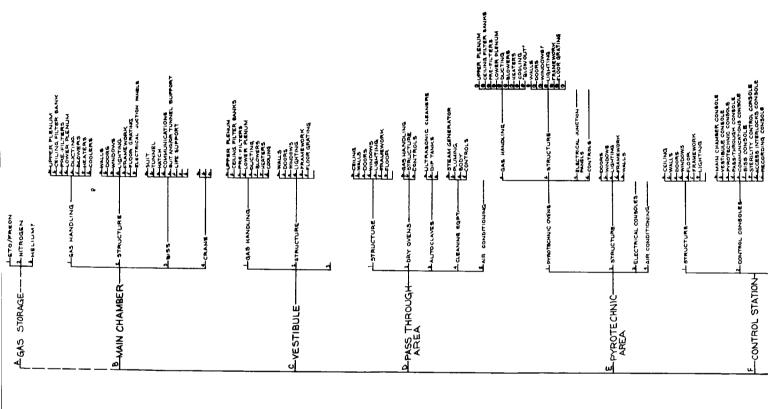


FIGURE E-4 ASSEMBLY/STERILIZER FACILITY PERSONNEL--TYPES, PIGURE E-4

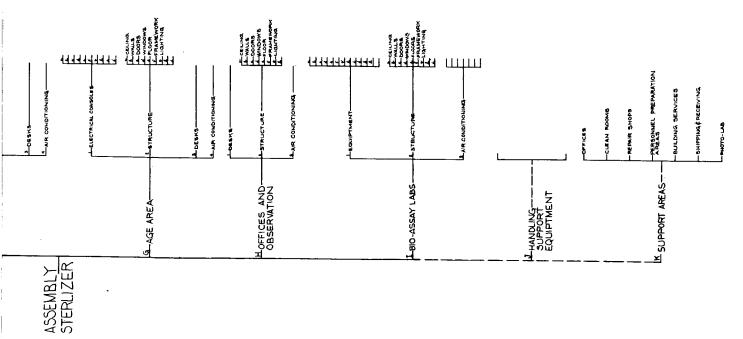
3) FACILITY EQUIPMENT COMPLEMENT

The area and equipment complements of a full Assembly/Sterilizer are represented in figure E-5 and table E-3. Figure E-5 provides the data in a facility equipment generation breakdown format with emphasis on the Assembly/Sterilizer proper. Table E-3 lists the elements of the full facility and provides equal emphasis on all the elements of the facility. This data identifies the several elements which must be integrated to provide a complete practicable facilty.

The headroom requirements for the several areas are given in table E-4







Below is a checklist of the elements considered essential for the Assembly/ Sterilizer Facility. Some descriptive remarks are also included.

TABLE E-3 ELEMENTS OF ASSEMBLY/STERILIZER FACILITY

Element

Assembly/Sterilizer A/S main chamber A/S Vestibule Pyrotechnic Oven Pass-Through Area BISS

- f) Control & Observation Area
 g) RF Equipment Area
- 2. Clean Room (Class 100)
 - a) Control & Observation Area
- 3. Precleaning Area
- 4. Air lock(s)
- 5. Pyro Receiving Area
- 6. Pyro Preparation Area
- 7. AGE Area(s)
- 8. Bio-assay Lab
- 9. Component Repair Area
- 10. Stockroom
- 11. Receiving Area
 a) Storage and Inspections

Remarks

Consists of several integrated elements.
Size approx. 72' x 100' x 30' (ceiling ht)*
Size approx. a 24-ft. cube
Size approx. a 12-ft. cube
Contains small autoclaves and ovens
Connected to A/S chamber for sterile working
Located for monitoring A/S chamber
Room connected by test cables to A/S chamber

Same size as A/S chamber and used for presterilization checkout work.

Provide overlook of clean room and main chamber.

For all hardware entering clean areas. On same floor as clean room and A/S chamber. Headroom sufficient for complete vehicle.

Required between clean areas and non-clean areas.

A separate explosive safe area.

Prepare pyro components for pyro oven. Minimum storage requirement. ESA criteria.

Convenient to assembly areas. Desirable to combine common AGE.

Convenient to the clean room. A pass-through interface is optimum.

Minor repairs and tools.

Cleaned parts storage.

Able to handle complete vehicles. Part of receiving area.

^{*} Building Layouts A & B following are based on 72' x 96' x 48' (ceiling height). These layouts were made before the 30' ceiling height and 20' longitudinal grid for the main chamber were established.

TABLE E-3 (Continued)

Element_

- 12. Shipping Area
 - a) Storage and Inspection
- 13. Maintenance Area
- 14. Personnel Preparation Area(s)
 - a) Locker Room(s)
 - b) Toilets and showers
 - c) Medical Inspection
 - d) Sterile Garments
 - e) BISS Garments
 - f) Lab Garments
 - g) Used Garment Room
- 15. Emergency Room
- 16. Office Area
- 17. Personnel Services*
 - a) Lobby
 - b) Lunch/Vending Area
 - c) Dispensary
 - d) Communications
 - e) Security Area
- 18. Building Services and* Utilities
 - a) ETO/FREON System
 - b) Nitrogen System
 - c) Utility Areas
 - d) Corridors, stairways, elevators, toilet rooms

Remarks

May be combined with receiving area. Part of shipping area.

Shop for building and equipment maintenance.

For technicians in clean room and BISS.
Storage of street clothes
Clean room and BISS personnel must shower.
Examine personnel for clean room and BISS work
Requires Class 100 cleanliness and direct
access to clean room
Sterilization not essential
No sterilization requirement

Garments collected for sterilization and

Locate in BISS area for first aid.

For administrative functions.

reissue.

Necessary for personnel functions. Entrance area for the building Convenient for all personnel Medical services Communications equipment center As required for plant security

Necessary for operation of the facility

For decontamination process
For sterilization process
For mechanical and electrical equipment
As required to suit building plan and
occupancy.

^{*} Specific areas for some of these services have not been allocated in all building layouts.

TABLE E-4 BUILDING HEADROOM REQUIREMENTS

Category	<u>Headroom</u> (Note 1)
A/S Chamber and Class 100 Clean Room	High, 30' clear (2)
A/S Vestibule	High, 24' clear
Precleaning Area	High, 24' clear
Shipping and Receiving	High, 24' clear (3)
Air Handling Equipment Rooms	High, 18' clear (4)
Shops and Laboratories	Low, 12' clear
Lockers & Personnel Preparation	Low, 10' clear
BISS	Low, 10-12' clear
Offices and Services	Low, 10' clear

NOTES:

- (1) The basic vertical building grid for these headroom requirements would be 15 feet and multiples thereof.
- (2) 30' height for horizontal positioning of in-process flight vehicle sections 48' for vertical positioning.
- (3) Overhead crane, if required, would have to be added to this height.
- (4) Not including any air-conditioned space under the insulated blowers in the heated gas stream within the heated "skin".

4) FLOOR PLANS AND ELEVATIONS

Eight different building plan arrangements, designated A through H, have been formulated. The intent has been to provide a wide enough basis of comparison between alternatives to permit recommendation of the best layout or layouts. Figure E-6 provides a key to the eight building plans. These plans differ in three major respects:

- . Material and personnel flow patterns
- . Relationship of clean room and Assembly/Sterilizer to each other
- . Relationship of clean room and Assembly/Sterilizer to ancillary chambers and support areas.

The building plans are presented in figure E-7 through E-20. Table E-5 compares the plans on the basis of several of the more significant functional parameters of the facility. A dimensional comparison of the plans is provided in table E-6.

Several additional building plans were considered in the formulation of the eight plans described herein. None of these additional plans appeared to offer any significant advantage over the plans described.

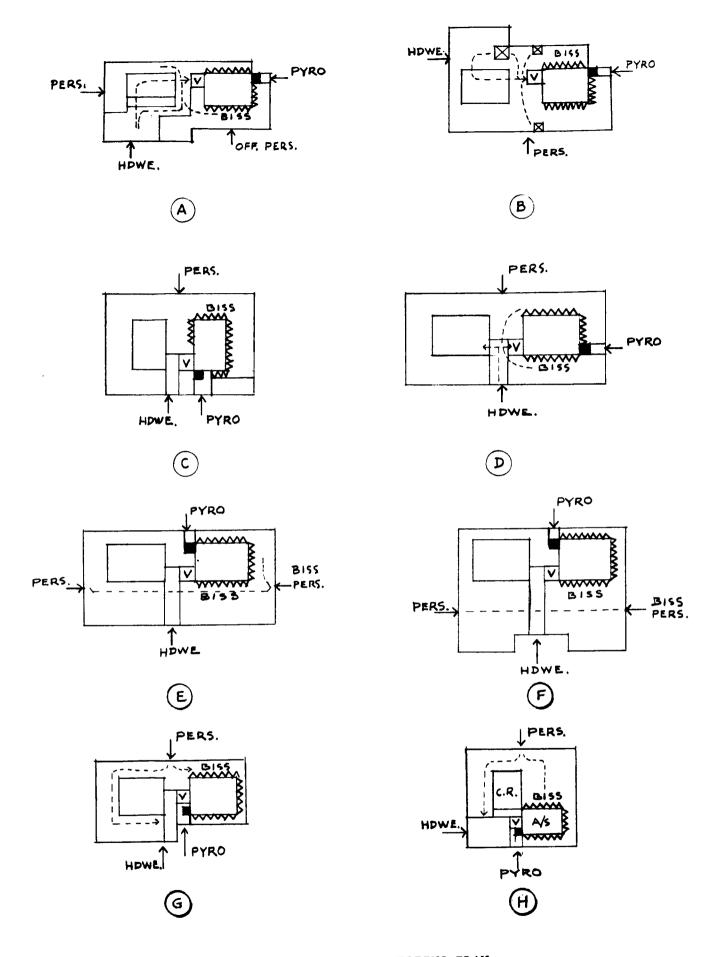
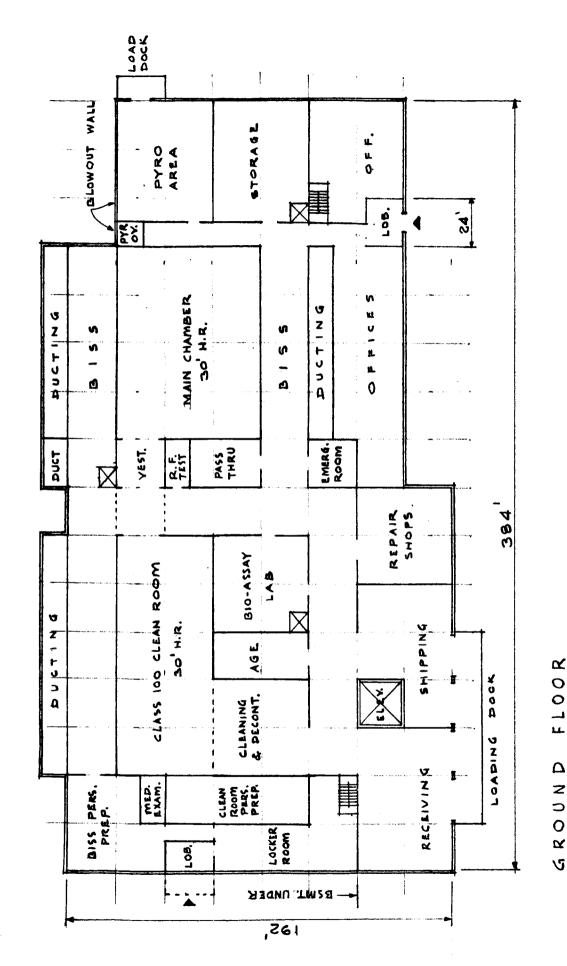
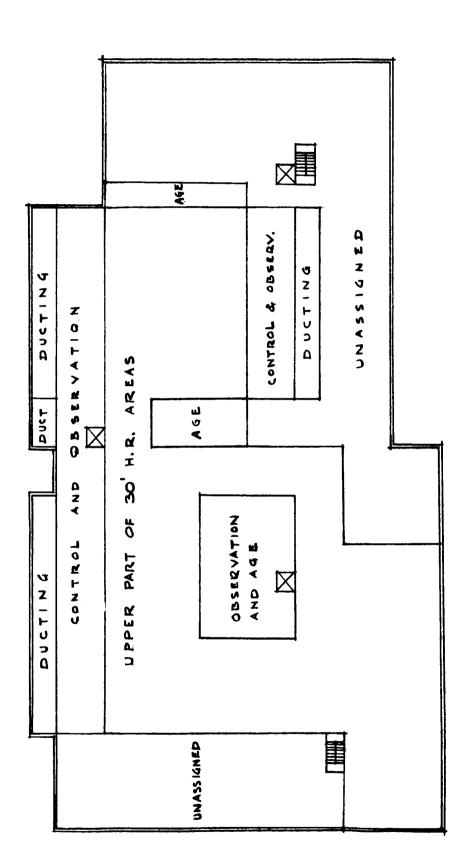


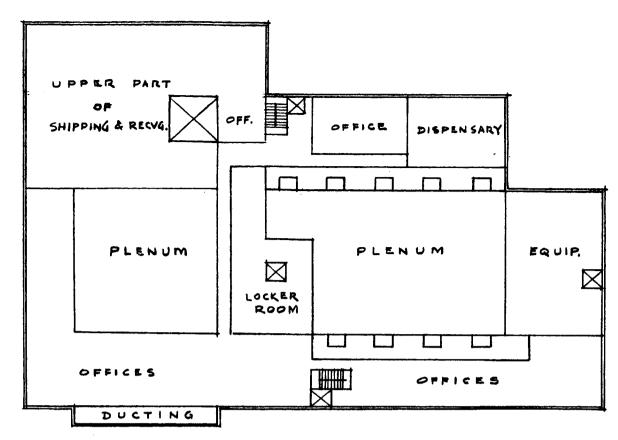
FIGURE E-6 KEY TO BUILDING PLAN



FLOOR Δ ROCN S



SECOND LEVEL



2 ND LEVEL

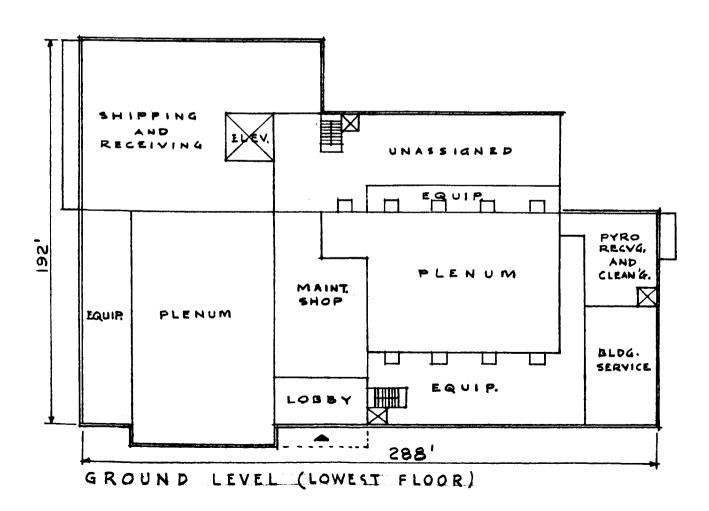


FIGURE E-9 A/S FACILITY PLAN B

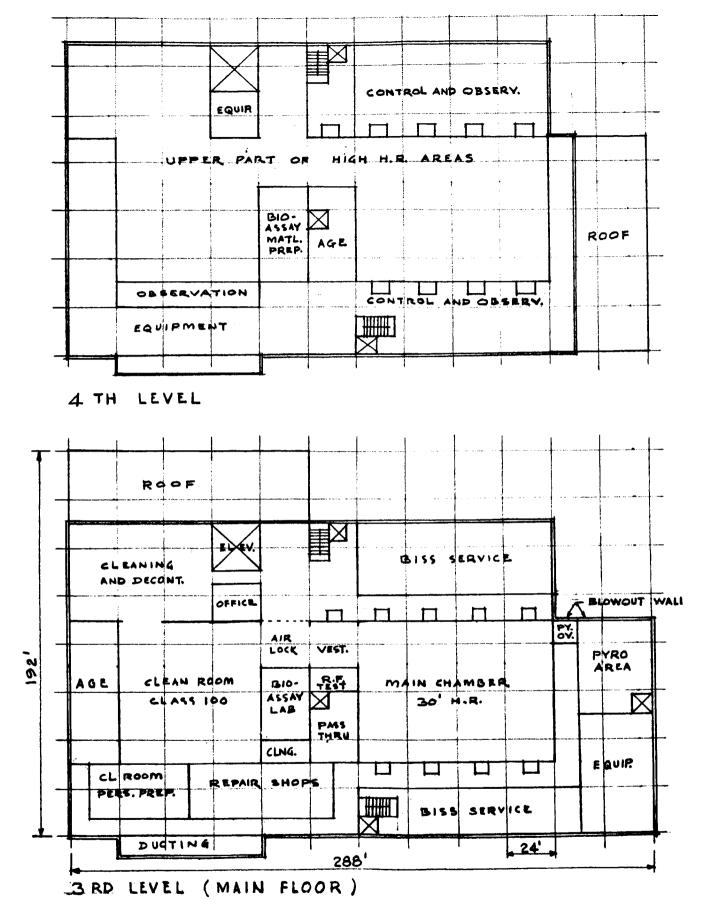
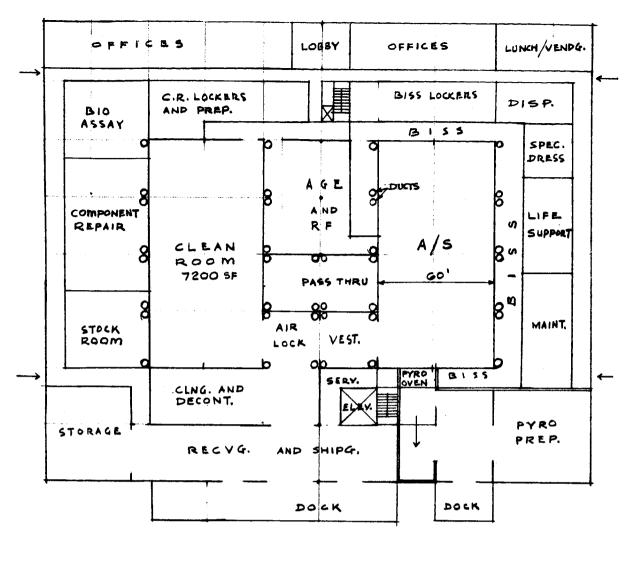


FIGURE E-10 A/S FACILITY PLAN B



GROUND FLOOR

240 × 280 1

0 50 FT

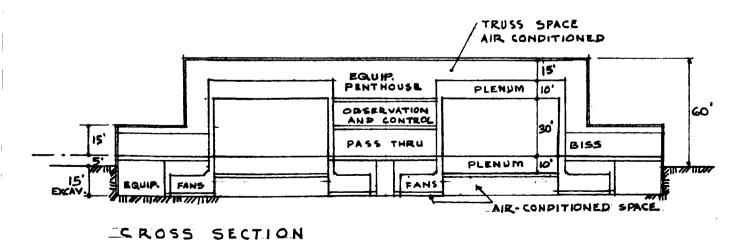


FIGURE E-11 A/S FACILITY PLAN C

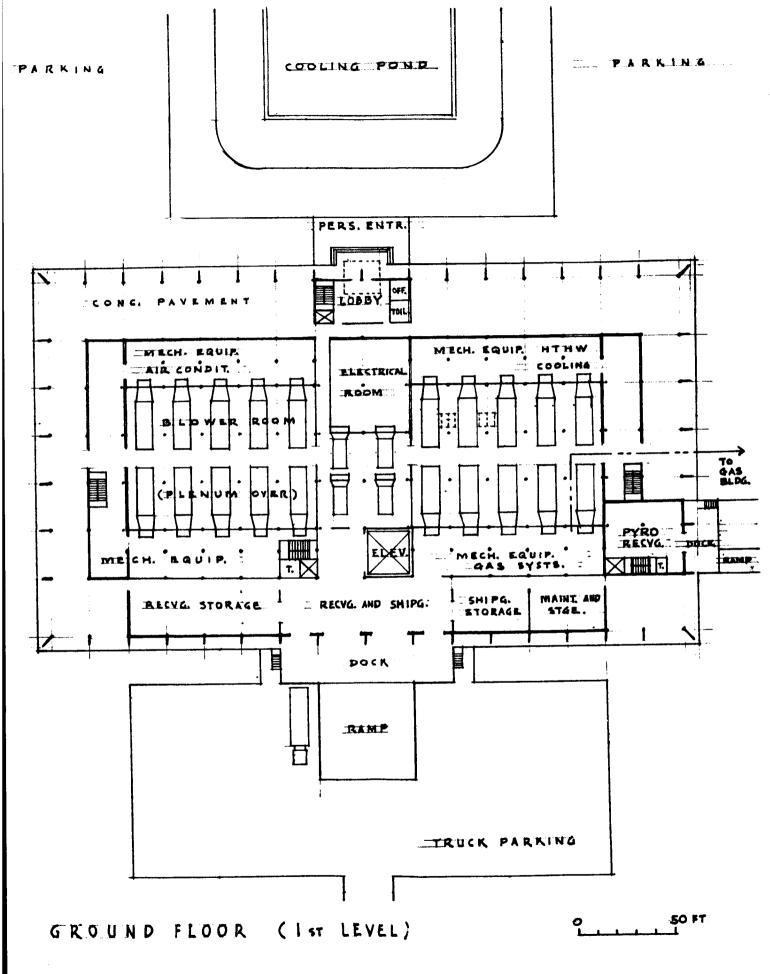


FIGURE E-12 A/S FACILITY PLAN D

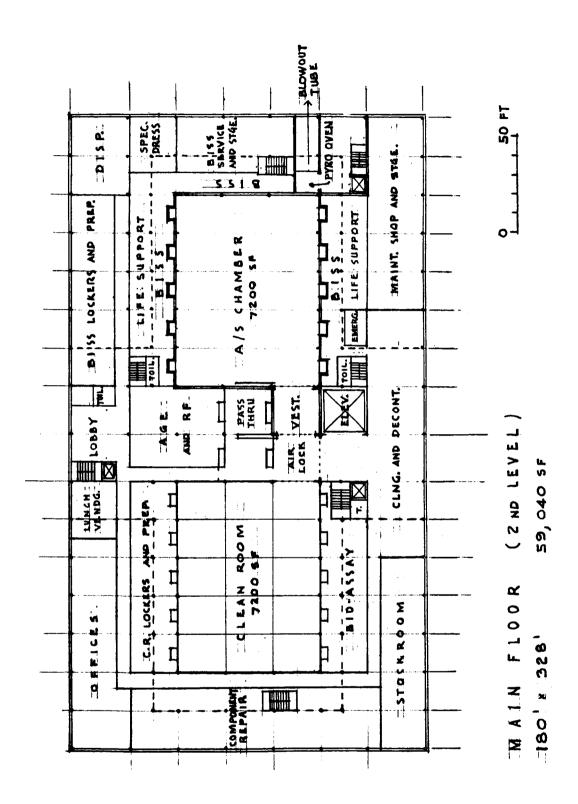
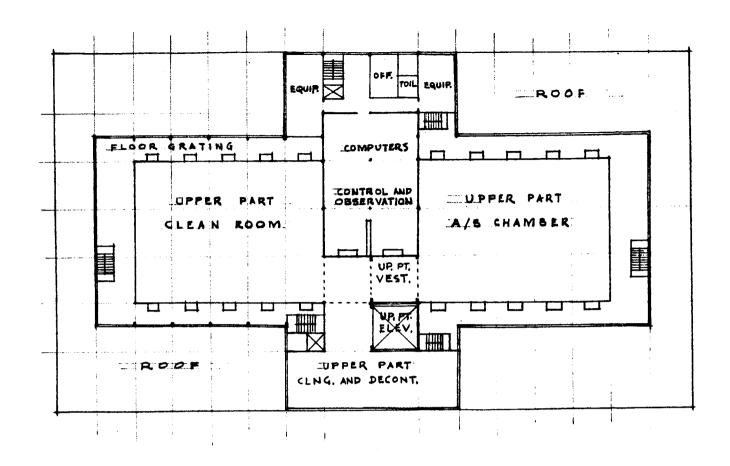
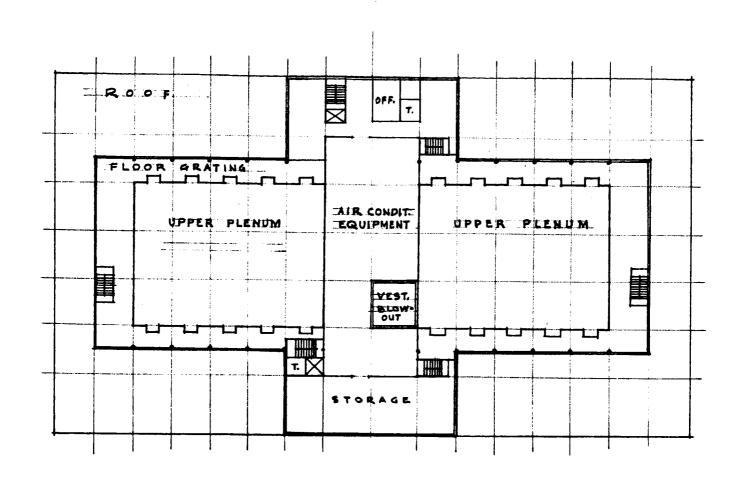


FIGURE E-13 A/S FACILITY PLAN D



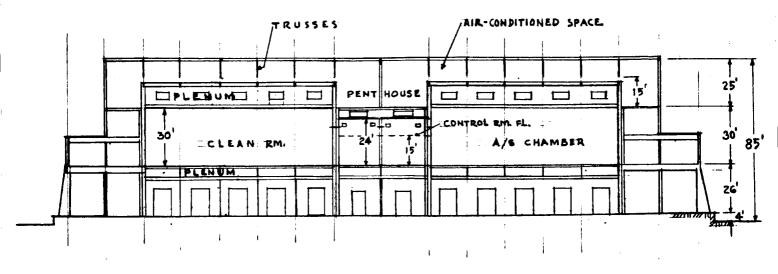
CONTROL ROOM (3RP LEVEL)

FIGURE E-14 A/S FACILITY PLAN D

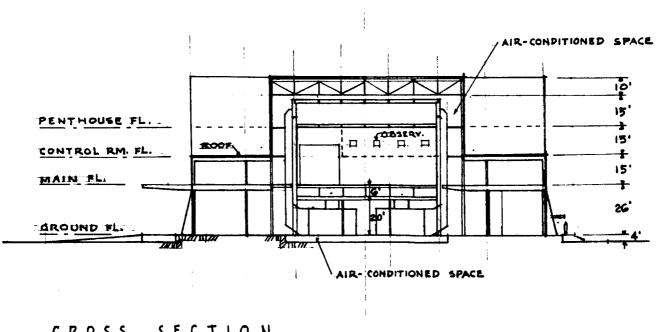


PENTHOUSE (4TH LEVEL)

FIGURE E-15 A/S FACILITY PLAN D

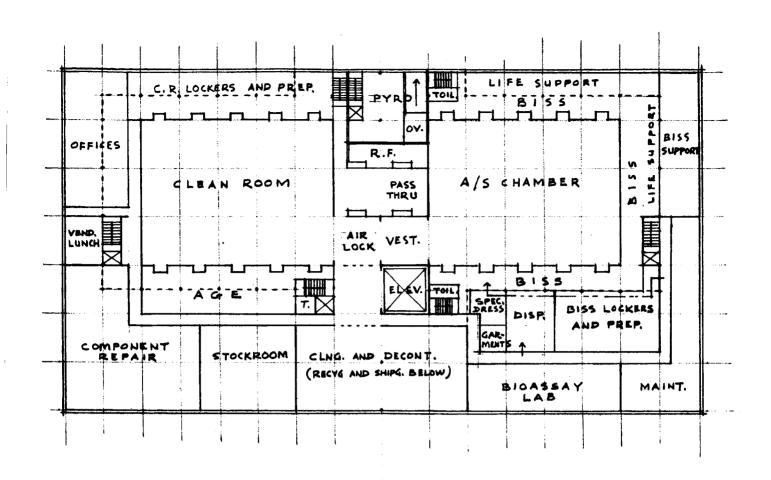


LONGITUDINAL SECTION



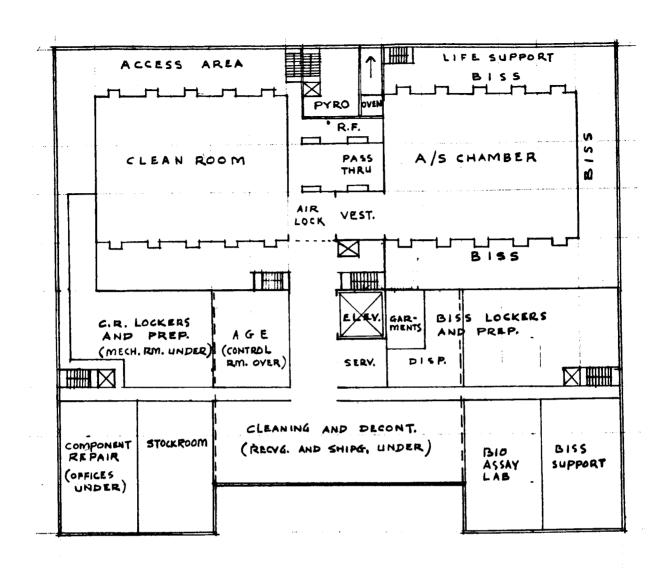
CROSS SECTION

FIGURE E-16 A/S FACILITY PLAN D



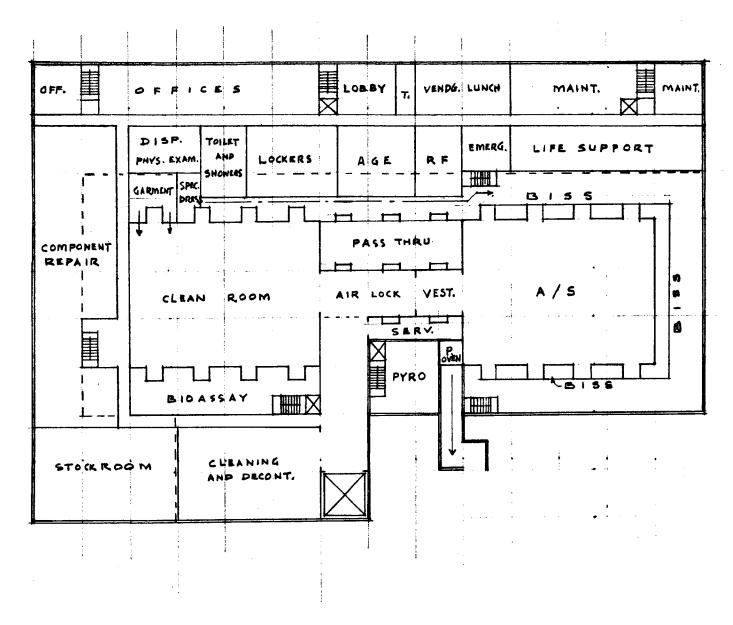
MAIN FLOOR (2ND LEVEL) 0 50 FT

FIGURE E-17 A/S FACILITY PLAN E



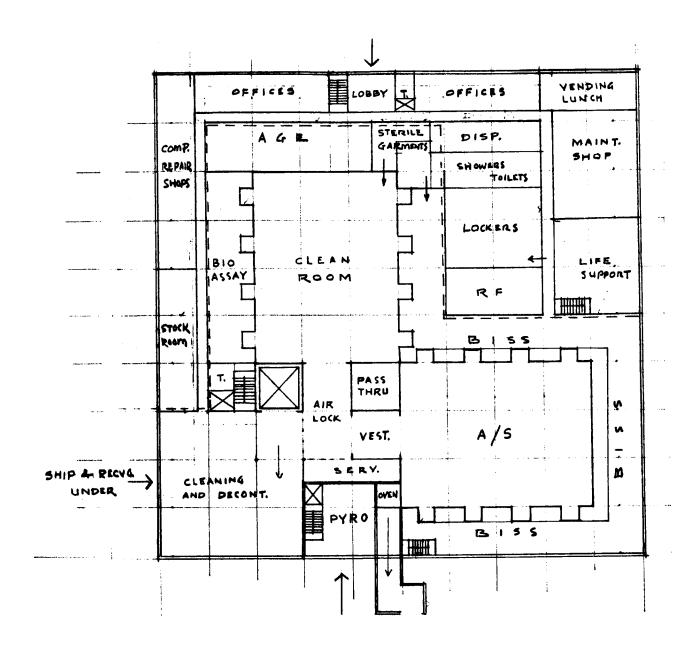
MAIN FLOOR 240' × 288'

FIGURE E-18 A/S FACILITY PLAN F



MAIN FLOOR 228' x 336'

FIGURE E-19 A/S FACILITY PLAN G



MAIN FLOOR (2ND LEVEL) 240' × 240'

FIGURE E-20 A/S FACILITY PLAN H

	COMPARISON PARAMETER	PLAN A	PLAN B	PLAN C	PLAN D
1)	Main Floor Location	At grade	Above grade	At grade	Above grade
2)	Shipping/Shipping Location	At grade	At grade	At grade	At grade
3)	Blower Assembly Location	Below chambers (below grade)	Below chambers (at grade)	Outboard (above grade)	Below chambers (at grade)
4)	Excavation Requirement	Yes - 24 feet	No	yes - 15 ft	No
5)	Ducting Plan	Outboard	Inboard	Inbo ar d	Inboard
6)	Personnel/Material Flows	Significant Crossing	Negligible Crossing	Slight Crossing	Significant Crossing
7)	Personnel Prepara- tion Areas	Common - one location	Separate for clean room	Separate for clean room	Separate for clean room
8)	BISS Areas	Connected by corridor on main level. Full access to both sides of main chamber.	Connected by corridor below main floor. Full access to both sides of main chamber.	Single contin- uous area. Access lost on more than ½ of side of main chamber.	Connected by corridor below main floor.
9)	Pyro Area	At grade -well isolated from RF and personnel	Above grade - well isolated from RF and personnel.	At grade -good isolation from RF -fair personnel isolation.	Above grade-good isolation from -RF -fair personne isolation.
	AGE Interface - Main chamber Clean Room	good good	good good	poor good	good poor
11)	Bio-assay Lab Inter- face				
	Main Chamber Clean Room	Fair good	good good	poor fair	poor good

12)	COMPARISON PARAMETER Monitoring Provisions	PLAN A	PLAN B	PLAN C P
	Main Chamber	good	good	good
	Clean Room	good	good	good
	Other		Multilevel personnel flow employed to op- timize material flow. Best repair shop in- terface. Best Cleaining inter faces.	

PLAN E	PLAN F	PLAN G	PLAN H
Above grade	Above grade	Above grade	Above grade
At grade	At grade	At grade	At grade
Below chambers (at grade)	Below chambers (at grade)	Below chambers (at grade)	Below chambers (at grade)
No	No	No	No
Inboard	Inboard	Inboard	Inboard
Significant Crossing	Significant Crossing	Slight Crossing	Significant Crossing
Separate for clean room	Separate for clean room	Separate for clean room	Common - one location
Single continu- ous area	Single continuous area.	Single continuous area.	Single continuous area.
Above grade- poor isolation from RF and personnel.	Above grade-poor isolation from RF and personnel.	Above grade-good isolation from RF fair personnel isolation.	Above grade-good isolation from RF fair personnel isolation.
poor good	poor poor	poor poor	poor good
poor poor	poor poor	fair poor	poor good

TABLE E-5 (CONT'D)

LAN D	PLAN E	PLAN F	PLAN G	PLAN H
good good	good good	good good	good good	good good
*Alternate connection across material flow or around perimeter.	- Plan D.	f Modification of Plan E.	Personnel and material areas on opposite sides of building -long personnel flow paths.	Poor chamber RF interface

DIMENSIONAL COMPARISON OF ASSEMBLY/STERILIZER FACILITY BUILDING PLANS TABLE

ж	240	240	57,600	85	3,700,000	4,032	4,032	**57,600	44,352	
ტ	228	336	67,536	85	4,600,000	7,500	5,800	**67,536	67,536	
ĬΈ	240	288	66,048	85	4,500,000	8,000	8,000	**66,048	66,048	
田	168	328	55,104	85	3,800,000	8,000	8,000	**55,104	55,104	1
D	180	328	59,040	85	3,600,000	10,000	10,000	**59,040	44,160	-
ပ	240	280	67,200	09	3,400;000	 	10,800	10,800	**67,200	50,400
В	192	288	47,376	85	3,600,000	25,000	14,400 **43,000	39,000	47,376	!
¥	192	384)* 70,272	ed 72	luding 5,000,000	(SQ.FT.)	14,400	21,000	**70,272	56,448
	Building Dimensions Width (ft.)	Length (ft.)	Ground area (sq. ft.)* 70,272	Height (Ft., measured from ground line)	Cubage (cu.ft., including Sublevel) 5,000,000 3,600,000	Building Floor Space (SQ.FT.) 4th Level	3rd Level	2nd Level	Ground Level	Sublevel (Basement)

110,016 148,372 148,096 126,208 123,200 TOTAL FLOOR SPACE 161,720 154,376

* Note that ground area is, in general, not the product of width times length since floor plans are not all rectangular.

** Main building level.

5). EVALUATION OF BUILDING LAYOUTS

Based on the plans and comparisons of the preceeding section, a tentative selection of the preferred layout can be made. Since no building layout can optimize all facility parameters, a weighting is necessary for trade-off between alternative plans. Such a weighting could be made on a numerical basis, but a subjective weighting can also serve to reduce the number of plans to a few most favorable ones. Further, it is possible to eliminate several of the plans on the basis of one or more significantly undesirable features. The plans that can be eliminated on this basis are listed below with the reasons for rejection.

- Plan A Rejected because outboard ducting significantly increases thermal and structural design difficulty as well as construction costs.*
- Plan C Rejected because of loss of BISS Access to one side of the Assembly/Sterilizer main chamber.*
- Plan E Rejected because of poor isolation of pyro area, poor bio-assay lab interfaces, poor AGE interface, and significant crossing of material and personnel flows.
- Plan F Rejected for same reasons as plan E.
- Plan G Rejected because of inefficient personnel flows, poor AGE interfaces, and poor bio-assay lab interfaces.
- Plan H Rejected because of significant crossing of personnel and material flow; Inefficient personnel flows; and poor interfaces between the Assembly/Sterilizer main chamber and the bio-assay lab, AGE, and RF areas.

Rejection of plans A, C, E, F, G, and H leaves only plans B and D in consideration. However, the selection of these two plans should also be examined in terms of the dimensional comparison of plans as shown in table E-6.

In making a selection of plans on the basis of a dimensional comparison, consideration must be given to which dimensions are to dominate the trade-off. For example, plan H has significantly smaller total floor space that plan C, but has a higher cubage. Inconsistencies of this type derive from several causes.

(1) In none of the buildings is the full potential floor space developed.

^{*}The fact that plans A and C both require excavation was not considered in this rejection because the ground datum line can be adjusted to any level on all of the plans without a fundamental charge in concept.

- (2) The volume of the building is predicted to a large extent on the main level floor area and the height required for the Assembly/Sterilizer main chamber and bio-clean room.
- (3) The allocation of footage to a specific function is not constant for all plans.

Thus, it is suggested that the optimum choices for trade-off on the basis of dimensions are main level floor area and building cubage. On this basis, plan B clearly stands out as a desirable choice, while plan D shows no marked advantage over the other plans.

Although the main level floor area of plan B is only about 73% of the main level floor area of plan D, its total floor space as shown in table E-6 is 125% of the floor space of plan D. In plan B, considerable floor space has been set aside as office, unassigned, and equipment areas whose specific purposes are not well defined at this time. It is felt that the conservatism applied in setting aside these areas will be shown to be justified as the facility and its functions are studied further.

6) CONCLUSIONS

The facility layout should be designed to optimize material flow to the maximum extent that achieving a reasonable personnel flow permits.

A multilevel facility is required. Thus, large equipment handling elevators are a necessity. Further, placement of all support areas on the main level with the Assembly/Sterilizer is not optimum.

To achieve optimum material and personnel flows, the Assembly/Sterilizer and its support areas (labs, shops, and personnel areas) must be integrated into a single facility.

For siting at Kennedy Space Center, the facility should require a minimum of excavation. Thus, the main level of the facility will be above grade. All building plans studied are of this form or can be adapted to this form.

Building volume is relatively independent of building layout. Building ground space and total floor space are not. Ground space is a direct function of main level layout. Total floor space is more a function of the space allocated to each of the primary and support function areas in the building.

While it is desirable to have a continuous BISS area, to do so compromises the isolation of the pyro areas from personnel and/or RF equipment. This isolation of the pyro areas should take precedence.

The best layout for gas handling equipment for the sterile chambers is achieved with blowers below the chambers and inboard vertical ducts running along the outer chamber walls.

Roofs over areas other than the clean room and Assembly/Sterilizer main chamber need not be taken to the full height of the roofs required over these chambers. However, it may be more economical to do so.

Building Plans B and D appear to offer the greatest promise of future study, with plan B appearing most advantageous.

The layout of a practical Assembly/Sterilizer facility building is feasible.

3. ENGINEERING DESIGN ANALYSIS

Engineering analyses were conducted during the course of the program in four general areas:

- (1) Gas movement and Filtration
- (2) Gas Supply and Management
- (3) Thermal Control
- (4) Structures

Effort was centered on identifying design problems and possible alternative solutions where applicable.

A. GAS MOVEMENT AND FILTRATION

The ducts, plenum, filters, and blowers for the laminar flow in the main chamber and vestibule must be able to operate satisfactorily in the four environmental modes described in 2B6 herein. The design objective for this laminar flow is:

Filtration: Adequate to product a class 100 environment (absolute filters - 99.97% effective against particles 0.3 micron or larger)

Velocity: Controllable from 10 to 100 feet per minute (nominal 90) uniformity of <u>+</u> 15% throughout the undisturbed room area.

1) Ducting and Plenums

Physical relation of the plenums, ducts and air handling equipment are a determining factor in selecting the configuration of the Assembly/Sterilizer chamber and supporting areas. There are three primary objectives to be met in establishing the configuration.

- (1) The ducting arrangement must provide an efficient flow so that system positive pressure is maintained without exceeding the pressure specified for the main chamber.
- (2) Location of ducts and air handling equipment must not interfere with work areas, or equipment such as BISS, related to the Assembly/Sterilizer chamber.
- (3) The arrangement must result in a practical building facility.

In selecting a general ducting layout for the main chamber, twelve alternatives were considered. These are shown in Figure E-21. Ducting layout plans 1 through 8 are low velocity ducts and plans 9 through 12 are high velocity ducts.

Plans 1 through 4 are ruled out by the necessity to have access to all walls of the chamber for operational reasons.

In selecting between 5 and 7 or 6 and 8, the choice is largely one of building layout convenience and cost. In selecting within 5 and 7 or 6 and 8 the choice becomes a trade-off of plenum size vs. ducting complexity. The longer the run from ducting outlet to the far end of the plenum, the more difficult it is to balance air flow out of the plenum and the larger the ratio of plenum depth to run. Thus, plans 5 and 6 will require respectively deeper plenums than plans 7 and 8, and will result in costlier buildings.

In selecting from plans 9 through 12 the case is somewhat modified. Using high velocity ducts contiguous to chamber walls does not completely obstruct those walls for other purposes. With basic chamber layouts as shown in the building layout plans in section 2E4, the choice in ducting plans clearly in favor of plan 9 or plan 10 since this is least disruptive to practical utilization of main chamber wall space. Plans 11 and 12 require longer ducting runs than 9 and 10 and offer no benefit if either 9 or 10 can be worked into a useable building layout.

Spaces 24 feet high were initially allocated above and below the main chamber (and bio-clean room) to accommodate plenums. This space is more than adequate. Whitfield* gives a ratio of 4/1 as the maximum ration of run/height for laminar flow system plenums,** Using this rule of Thumb, the plenum run and minimum height for each of the ducting plans of figure E-21 is given in the following table.

TABLE E-7
PLENUM RUN AND MINIMUM HEIGHT

(Chamber 72' x 96')***

<u>Plan</u>	Run (ft)	Min. Plenum Height (ft)
1,7,10,12	48	12
2,8,9,11	36	9
3,5	96	24
4,6	72	18

Note that in plans 5,6,7,8,11, and 12 it is necessary to provide additional ducting from the outboard risers to the plenums (this is not part of the plenum run).

^{*} W.J. Whitfield et al; Basic Design Requirements for Laminar Air Flow Dust Control Devices; Sandia Corp. Reprint SC-R-64-145A, May 1964.

^{**}Other sources allow ratios as large as 10:1
***Chamber size was changed to 72' x 100' as a result of structural analyses
performed later in the study. This change does not materially affect these
results.

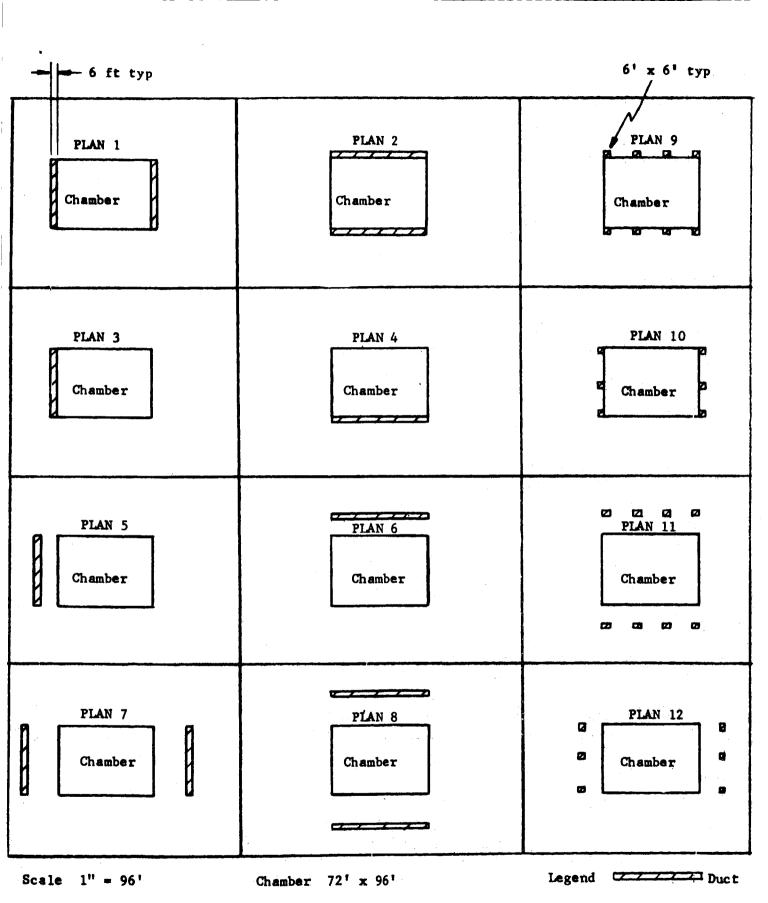


FIGURE E-21
ASSEMBLY/STERILIZER MAIN CHAMBER
DUCTING LAYOUT ALTERNATIVES

For a main chamber floor space of 6912 square feet, and a 100 fpm laminar flow, the gas flow rate is 691,200 cfm. For the ducting plans shown in figure E-21, this results in the following flow condition in the ducts.

TABLE E-8
FLOW CONDITION IN DUCTS *

Plan	Flow Per Duct (cfm)	Velocity in Duct (cfm)
1,7	345,600	800
2,8	345,600	600
3,5	691,200	1600
4,6	6 9 1,200	1200
***9,11	86,400	2400
10,12	115,200	3200

^{*} For 100 fpm in main chamber

All of these velocities are within the limits established by ASHRAE,** as reproduced in part in Table E-9.

TABLE E-9

DESIGN VELOCITIES FOR CONVENTIONAL AND HIGH VELOCITY AIR MOVEMENT SYSTEMS*

DUCT ELEMENT	Conver Public Bu Normal	ational aildings Max.	Industrial Normal	_	Velocity Comm. Bld Normal	gs. Max.
Main Ducts	1000	1600	1500	2200	2500	6000
Fan Outlets	1500	2200	2000	2800	2500	5000
Outside Air Intakes	500	900	500	1200	600	1000
Filters	300	350	350	350	350	350
Heating Coi	ls 500	600	600	700	600	700

^{*} From Buffalo Forge Co. adaptation of ASHRAE data.

^{**} ASHRAE "Heating, Ventilating, and Air Conditioning Guide", p. 303.

^{***} The chamber size change to 72' x 100' results in a longitudinal grid of 20 feet, thus there are 5 riser ducts per side for plans 9 and 11 rather than 4. Each of these ducts is 6' x 6' and has a flow velocity of 2000 fpm.

Since discrete blower assemblies are necessary, the discrete ducting plans (9, 10, 11, and 12 of figure E-21) are most satisfactory for incorporation in a complete gas movement system. Also, it was determined in the building layout studies that no significant advantage was gained by having the ducts outboard; while having the ducts inboard significantly reduces the structural and thermal problems in ducting design and construction. Thus plans 11 and 12 were deleted from further consideration.

In the study of building layouts, it was determined that the most advantageous ducting plan was that of plan 9. Thus, subsequent ducting studies were based on this general configuration (i.e. multiple, inboard, riser ducts on both sides of the chamber).

The next aspect of the ducting layout investigation was the interrelationship between ducts and BISS hatch in a typical wall module.
Four layouts of this interrelationship are shown in figure E-22.
From this figure with its summary comments, it is seen that the preferrable plan is for a single riser in the middle of each module. This
leaves approximately seven feet on either side of the riser for BISS
interface.

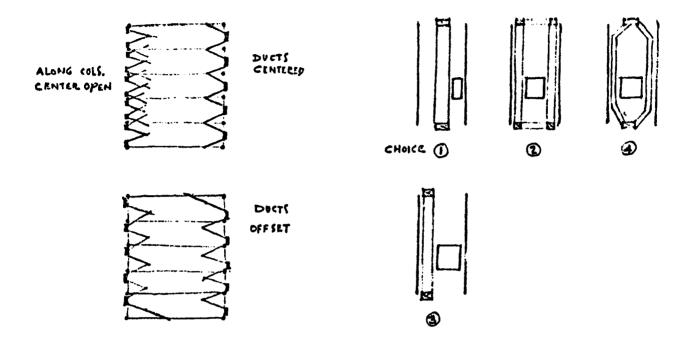
The relationship of inboard ducting to the overall configuration is shown in three alternate transverse elevations in figure E-23. Each elevation reflects close coupling of the chamber ducts and air handling equipment. Location of air handling units on the same level as the chamber floor increases problems in the duct system and makes access more difficult for BISS and other elements related to the chamber work area. Accordingly all arrangements keep the main floor level free of blower equipment.

Elevation 1 places the fans under the lower plenum. The total system is contained inboard. Fans are close to the chamber floor, where minimum pressure is essential. Floor height is a consideration.

Elevation 2 places the blowers over the upper plenum. Equipment maintenance, mechanical services, and accessibility would be more of a problem. The main floor is closer to ground level.

Elevation 3 shows the blowers mounted outboard of the chamber. Overall building height is reduced. Air flow is more involved and less favorable.

Based on these considerations, the plan shown in elevation 1 is preferable from the standpoint of gas flow and elevation 3 is preferable from the standpoint of BISS interface compatibility. Selection between these two layouts requires further definition of the BISS interface requirements and the effects of assymetrical ducting on gas flow. Figure E-24 gives approximate dimensions and spatial relationships for the ducting, for the selected elevations.



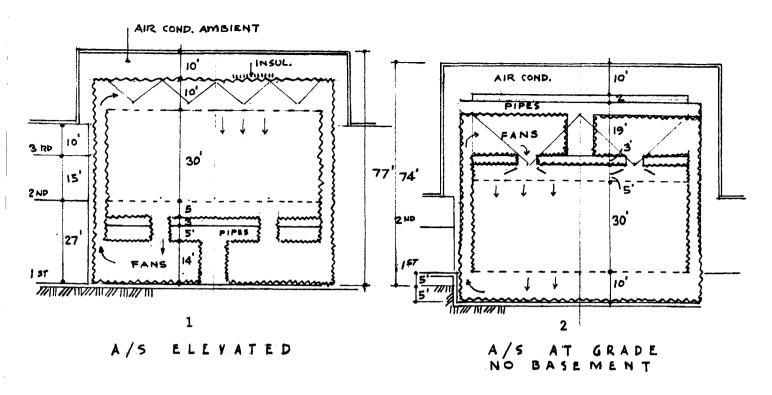
- D SIMPLEST AIR SYSTEM. SYMMETRICAL. LIMITED SIZE OF SIDE OPENINGS.
 FIRST CHOIL IF NO NEED FOR LARGER SIDE OPENINGS. ENTER ON ENDS.
- DOUBLES NUMBER OF UNITS. SYMM. (2 DUCTS PER BAY). GOOD SIDE OPCHING.

 GOOD LINEAR DISTRIBUTION. OF AIR. BRINGS COLS. UP TO TEMP.

 PREFERRED IF LARGE SIDE OPNGS. ARE REQUIRED.

 SUB-PLENUM IS PRACTICAL. SMALLER EQUIP.
- (3) UNSYMMETRICAL DISTRIBUTION. GOOD SIDE OPENING.
- A SYMM. BUT MORE COMPLICATED. ADOD SIDE OPENING.

FIGURE E-22 DUCT SYSTEM/BISS INTERFACE TRADE OFF



WHOT STERILE SKIN

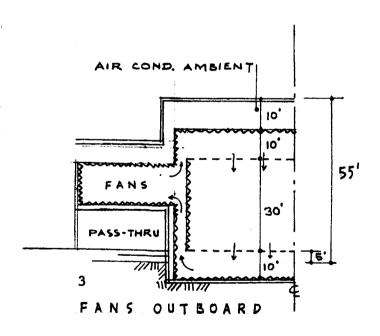
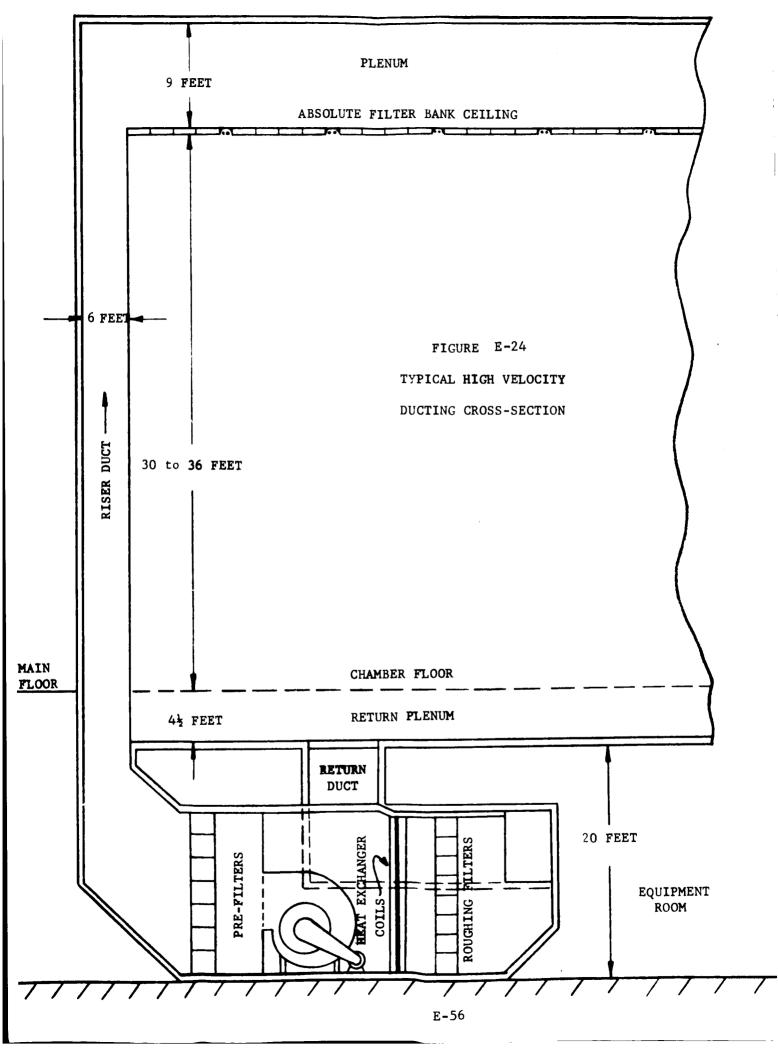


FIGURE E-23 A/S CONFIGURATIONS



Thus the recommended ducting plan is to use 10 inboard riser ducts contiguous to the chamber long walls. The risers are 6 feet wide by 6 feet thick and will be located in accordance with elevation 1 or 3 of figure E-22. Selection between these two elevations requires further study of the BISS interface and the effects of assymetric ducting on the uniformity of laminar gas flow in the chambers.

The upper plenum is nine feet high in accordance with the "Whitfield Criteria" of a ratio of run to depth of not more than 4:1. Since the return plenum exhausts from the center of its serviced area rather than from the periphery, this plenum will only need to be 4½ feet deep.

Below the return plenum, approximately 20 feet of clear space will be required to accommodate filter and blower housings and to permit servicing the equipment therein.

2) Filters

As shown in Figure E-24 the recommended plan calls for three sets of filters: roughing filters before the fan, pre-filters after the fan, and an absolute filter bank ceiling in the chamber. The filters recommended are:

Roughing - Union Carbide Company "Ulock" brand panel type using "Dynel Modacrylic" as a filter media from shall be cadmium plated steel.

Pre-Filters - Cambridge "Aerosolve 95" filters. Frames shall be cadmium plated steel.

Ceiling - Cambridge IE-600 "Absolute" Filters with aluminum separators and all-glass binderless media. Media adhesive will be glass mat and gaskets of fiberglass. Framing will be Ultracel I of aluminum or cadmium plated steel.

Three lighting systems were investigated for ease of integration with the ceiling filters with a minimum of disturbance of the laminar air flow. Sizing and distribition of the lights is planned to give a uniform illumination on the order of 100 foot candle at the floor level.

High-bay mercury vapor fixtures mounted above heat-resistant glass panels will do a satisfactory job. Mercury vapor has a rated life of approximately 16,000 hours, which is advantageous. However, since mercury light fixtures would require approximately 275 to 300 square inches of ceiling space for each fixture, disturbance of the air flow from the ceiling might present a problem.

The two most probable lights are fluorescent and GE Quartzline iodine vapor incandescent. The Quartzline appears most suitable because it has inherently higher temperature tolerance, it requires no ballast,

it has higher output for a given fixture size, and its electrical connections are more suitable to severe environment service. These fixtures could be designed to it between the supporting members of the ceiling filters thus requiring very little additional space and not obstructing the air flow.

It is indicated by Whitfield* that disturbance caused by light fixtures will dampen out approximately 3 fixture widths downstream from the fixture.

3) Blowers and Motors

The selection of a suitable blower system (blower, motor, dampers, and inlet boxes) is greatly complicated over that for a more conventional system. Fan catalog ratings are for standard air at 0.075 lb/ft³ density** (29.92 in Hg, 70° F dry bulb, and 50% RH). Further, the fan/motor selection is designed for maximum efficiency at one cfm rating for a specified total pressure (static plus velocity pressure).

Two types of fans which were investigated for applicability to the Assembly/Sterilizer were the backwardly inclined blade centrifugal and the axial, with the centrifugal as the best candidate. The selection of a fan system must satisfy the following requirements:

- . Operational range of 10/1 in max/min flow rates.
- . Handle gases ranging in density from N_2 at $300^{\circ}F$ to ETO/FREON at $70^{\circ}F$ (with the possible addition of He at $70^{\circ}F$ for leak checking).
- . Work against varying static pressure as filters load-up with particulate matter.
- . Contribute virtually no leak to the Assembly/Sterilizer.

The very low permissible leakage imposes a severe constraint on fan system design. Normally fan systems handling high temperature or otherwise antagonistic gases place bearings and motors outside of the air stream using shaft seals to minimize leakage. These seals have leakages on the order of tenths of a cfm - such leakage rates are wholly unacceptable for the present system. This means that the bearings and motors will probably have to be placed in the air stream.

Some of the variations in gas handling load can be compensated for by using inlet and/or outlet dampers on the fans. However, using both inlet and outlet dampers the range of compensation is from 100% of capacity down to a minimum of about 40%.** Thus it is likely that variable speed drives will be needed to satisfy the full range of gas handling conditions.

[★] W.J. Whitfield, et al; Basic Design Requirements for Laminar Air Flow Dust Control Devices; Sandia Corp. Reprint SC-R-64-145A, May 1964.

^{**} New York Blower Company Engineering Letter E-3-r

Gas movement analyses indicate the use of double width, double inlet backward inclined centrifugal fans of 54½" wheel diameter. Standard enclosed high temperature motors loaded to no more than 80% of name plate rating will be suitable as fan drives in the hot gaseous atmosphere of the sterilizer. The motors will have sealed ball or roller bearings using high-temperature fluorinated Hydro-carbon lubricants. The fan bearings will be similar. Gates Super Duty belts will meet the environmental operating requirements. At least one more than the required number of belts will be installed on each drive. The drive pulley will be adjustable.

It is conservatively estimated that the final drive requirements for each blower assembly will not exceed 100 horsepower including derating allowance for elevated temperature. Motors in this horsepower class, capable of operating at temperatures up to 300° F, are commercially available.

One further factor of importance is the stability of the blower system. Fans operating away from peak efficiency tend toward instability. In final design of the gas movement system this tendency must be guarded against.

B. GAS SUPPLY AND MANAGEMENT

The major gases identified for use in the Assembly/Sterilizer system are air, nitrogen, Freon-12, and ethylene oxide. (In addition a trace gas such as helium may be used for leak detection). The four basic environments to be established using these constituent gases are defined in section 2 B6.

1) Costs

All gases required for the Assembly/Sterilizer (other than air) will be purchased in bulk lots (tank cars). Prices for these gases from one supplier are:

Nitrogen (liquid) \$.25 per 100 cubic feet of STP gas *FREON-12 \$.263 per pound *Ethylene Oxide \$.27 per pound

These prices can be used to establish the approximate total gas costs for different system volumes and operating plans.

2) Gas Density Tabulations

As a ready reference in analyzing the Assembly/Sterilizer gas management systems, the following table is provided.

^{*} On-site mixing of these gases would be employed to obtain an 88%/12% (W/W) mixture.

TABLE E-10 GAS DENSITIES

GAS	TEMPERATURE	RH	PRESSURE	DENSITY
AIR	70°F	50%	29.92 in Hg	.075 #/ft ³
NITROGEN	300°F	0	29.92 i n Hg	.0495 #/ft ³
*ETO/FREON	70 ⁰ F	50%	29.92 in Hg	**.285
HELIUM	70°F	0	29.92 in Hg	.0101 #/ft ³

*ETO/FREON for 400 mg/liter of ETO at 130° F (approximately 450 mg/liter at 70° F)

**Water vapor contribution negligible - set equal to zero

From these data and goals for the system, the following criteria are established.

Design goal velocity ratio (main chamber) = 100/10 = 10/1Minimum acceptable velocity ratio (main chamber) = 100/25 = 4/1Design goal density ratio = .285/.0101 = 28/1Minimum acceptable density ratio = .285/.0495 = 5.75/1Design goal mass movement ratio = $10/1 \times 28/1 = 280/1$ Minimum acceptable mass movement ratio = $4/1 \times 5.75/1 = 23/1$

The gas movement system described above is compatible with the minimum acceptable mass movement ratio of 23/1. The extent to which the system capability would approach the design goal of 280/1 would have to be determined by a much more extensive analysis supported by experiment.

3) Purging

All purging of gases from the system will be accomplished by supplying the new gas and releasing the old gas while maintaining established system pressure. Purging will be done by supplying gas at approximately 70°F nominal. Two types of purging are considered: static displacement and dynamic mixing. With static displacement, the fans would be shut off and heavy gases would be admitted low in the system with the lighter gas drawn off near the top, and conversely. The dynamic mixing would consist of supplying all gases at one point in the system. The mixture would be drawn off at such a rate as to maintain constant system pressure. The dynamic mixing system will take less time to achieve moderate concentration of the new gas in the system, whereas the perfect static displacement will always use less gas to achieve a given concentration. The degree to which a practical system can approach the ideal of a perfect static displacement system would have to be determined by extensive analysis and laboratory evaluation.

The concentration of a gas constituent being purged into a constant volume, constant pressure system with complete mixing (i.e. mixed gas drawn off at the same rate as constituent is supplied) is

$$\frac{C-1}{Co-1} = e^{-kt}$$

where C = concentration (1.0 = 100%)

Co = initial concentration

From this equation the purging requirements for any desired concentration can be tabulated. This has been done in table E-ll assuming an initial concentration of zero.

TABLE E-11 CONCENTRATION OF A GAS CONSTITUENT AS A FUNCTION OF THE NUMBER OF SYSTEM VOLUMES OF GAS PURGED INTO A SYSTEM (NOTE 1)

SYSTEM		
VOLUMES OF PURCE		RESULTANT
OF PURGE		CONCENTRATION
GAS	e-kt	$C = 1 - e^{-Kt}$
<u>Kt</u>		
0	1.000	0
.1	.90484	.0 95 1 6
.2	.81 873	.18127
.3	.74082	.25918
.4	.67002	.32968
.5	.60653	.39347
.6	.54881	. 45 11 9
.7	.49659	.50341
.8	.44933	.55067
.9	.40657	. 59 343
1.0	.36788	.63212
1.5	.22313	<i>.</i> 77687
2.0	.1 3534	.86466
2.5	.08286	.91714
3.0	.0 4979	.95021
3.5	. 03 1 97	.96803
4.0	.01832	.98168
4.5	.01111	.98889
5.0	.00674	.99326
6.0	.00248	.99752
7.0	.00091	.99909
8.0	.00034	.99966
9.0	.00003	.99988
10.0	.00005	.99995
10.0		

Note 1: This table is based on a complete mixing system with initial concentration of zero.

A design goal of one system volume per hour has been extablished for purging the Full Scale Assembly/Sterilizer. Based on the criteria of the JPL Specification No. 50503-ETS, dated 12 January 1966, the nitrogen purge has been established to purge to .25% of residual gases. With a perfect dynamic mixing system, this would require six system volumes of nitrogen.

For the ETO purge for a concentration of 400 mg/liter at 130°F, the residual gases including water vapor for 50% RH would be 10%. This would require about 2.3 system volumes of ETO/FREON for a perfect dynamic mixing system.

At the completion of operations in the Assembly/Sterilizer, it will be necessary to purge air into any chamber which will be entered by personnel who are not protected by BISS suits. The criteria for the air purge is two-fold: The oxygen content of the resulting mixture should be not less than 18% oxygen by volume and the concentration of ETO should be less than 50 parts per million by volume.*

Analyses of the cost of the gases to accomplish the purging in a large chamber such as the Assembly/Sterilizer main chamber (approximately 400,000 cu. ft) strongly suggest that ETO/FREON not be used in the main chamber. Establishment of the 400 mg/liter ETO concentration at 130°F would require on the order of 2,000,000 cu. ft. of one ETO/FREON gas mix. Thus, unless an extremely efficient reclamation process is available, the economics of using ETO/FREON in the Assembly/Sterilizer main chamber is highly questionable.

4) Gas Reclamation

After the decontamination period of ETO/FREON cycle, the gas mixture must be contained, separated and salvaged for safety and economy. Further study of the economics of the various reclamation techniques is necessary, but it is recommended that the rationale underlying the techniques described below be given consideration.

- 1. ETO is highly toxic and should not be "dumped" to atmosphere.
- 2. ETO can be returned to vendor for possible salvage, or can be disposed of by controlled burning.
- 3. Controlled separation of the ETO/ $\rm H_2O$ vapor mixture from the freon may result in a moisture-free freon which could be further dried, compressed, and condensed for future use.
- 4. ETO has a relatively high (51.3°F) boiling point and should be easy to condense and collect by mechanical means.
- 5. Comparitively little additional equipment is required.

The salvage cycle for ETO/H $_2$ O vapor would be as follows: Close the fan vortex dampers to reduce the velocity through the coils. Introduce chilled water at $40^{\rm o}{\rm F}$ into the first coil downstream of the return gas to the fan housing. By slowing the gas flow and

*"Threshold Limit Values for 1965" by the American Conference of Governmental Industrial Hygienists.

using 40° water it should be possible to condense all the ETO. The liquified ETO/H₂O mix would then drain to a lift trap which would use nitrogen to pump the liquid into a suitable container for storage or return to vendor. After the gas has passed through the chilled coil, and condensation allowed to drop out, the remaining gas should be passed through a reheat coil to preclude the possibility of any further condensation taking place in other parts of the system. All components of the system which come in contact with the liquified ETO should be constructed of stainless steel to reduce the corrosive effect of concentrated ETO. During the time gaseous ETO/H₂O mixture is being condensed, the positive room pressure will be maintained by the introduction of dry gaseous nitrogen.

When the ETO condensation is complete, the Assembly/Sterilizer system will contain approximately 88% freon, 12% nitrogen and some water vapor depending upon the relative affinity for water between ETO and freon. This is relatively safe non-toxic mixture which could be purged to atmosphere should economics dictate; however, it would be possible to install condensing equipment to salvage a large percentage of the freon. This may be uneconomical considering the amount of equipment required to extract the freon while continuously purging the Assembly/Sterilizer system with nitrogen and at the same time keeping the purge time down within reason.

C. THERMAL CONTROL

System Concept

The Assembly/Sterilizer should be designed to provide the controlled environments defined in 2B6 above. A central accuracy of \pm 2°C is desired. Since the vehicle hardware and main chamber gas temperatures will be virtually identical in equilibrium, the gas temperature range and tolerance is defined the same as the hardware sterilization temperature, with higher temperatures in the "back loop" being acceptable. The permissible transient to go from ambient to sterilization temperature has been selected to be 25 to 50° F/hour.

Since the full inner portions of the main chamber and its associated duct work are to be sterile by definition, it is necessary that all walls, etc. be brought up to, and maintained at, the sterilization temperature with the flight hardware. Thus skin heaters for all walls etc. are required in addition to the heaters for the chamber gas. Heated walls constitute a rather delicate thermal balance problem.

It is normal practice in any control system to have sources of driving forces on either side of the system set point. In a thermal control system this means a heat source and a heat sink, with the heat source being hotter than control temperature and the heat sink being below control temperature. However, if the entire system must exceed a specified minimum temperature for a set time (sterilization), then the heat sink temperature becomes a controlling factor on the time that the rest of the system must remain at the elevated temperature. Consider the following example:

Heat Source temperature:	150° C
Set point temperature: (for 22 hours)	135° C
Heat Sink temperature:	120° C

If these specifications were considered to apply to a control system for the Assembly/Sterilizer, then at the end of the 22 hours there would still be a part of the system, the heat sink, which had not been exposed to the full sterilization treatment. To assure sterilization of the heat sink, a period of 84 hours would be required, thus exposing the flight hardware to almost four times the required duration at +135° C. This is contrary to the whole concept of the permissive definition of a range of sterilization treatments which allows the treatment least adversely affecting the flight hardware performance and reliability to be selected. Thus, the heat sink must be kept as close to gas temperature as possible.

Since the blowers are creating heat in the system, heat loss is required to maintain temperature equilibrium even with no intentional heat input (this argues in favor of having motors and bearings outside

of the chamber duct work).

A partial solution for this paradox suggested for the Assembly/ Sterilizer is to maintain gas temperature near the upper end of the tolerance band and to maintain the walls near the lower end of the tolerance band. This permits the walls to act as a heat sink for the system without compromise of sterility. Typically for a nominal set temperature of $+135^{\circ}$ C the gas might be maintained at $+136.5^{\circ}$ C with the walls at $+133.5^{\circ}$ C with a $+1^{\circ}$ C control accuracy on each. (This basic scheme was implemented in the Assembly/Sterilizer analog.) Additional heat loss would be provided, as required, by a heat exchanger in the back-loop of the gas recirculation system.

To obtain some further idea of the magnitude of the thermal control problem, it is worthwhile to consider the volume of the Assembly/ Sterilizer main chamber plus duct work and the square feet of controlled surface for a typical building layout. For building plan B the Assembly/Sterilizer main chamber system has a volume of approximately 400,000 cubic feet with total temperature controlled insulated surface area of approximately 60,000 square feet. While the volumes and areas in the back loop of the main chamber may be above the temperature set point without compromising sterility, there must be sufficient total area below the set point (but within 2°C tolerance) to act as a heat sink.

The skin of the walls, etc. would be heated either by electric heaters or high-pressure hot water heat exchangers such as Trantner Mfg. Company's Platecoils*. The electrical heaters would be easier to control but the high pressure water system offers much more uniform control which is essential to the overall thermal design. A major difference that exists between an electrically heated skin zone and a zone of plate coil is that the electrical heater provides a uniform power density heat input while the high pressure hot water system attempts to maintain a uniform temperature. The Platecoils* could also be structurally integral with the wall skin. At 300° F the pressure of the water would be approximately 67 psig which offers no problem since the Platecoils* are designed for applications up to 250 psig.

2) Heating and Cooling Loads

Based upon a requirement of outside skin temperature not imposing an excessive heat load upon the Air Conditioning system of the rest of the building, and a skin temperature not uncomfortable to the touch, it is recommended that an insulated sandwich panel having a total U factor of 0.08 be used. This factor will limit the outside skin

^{*} Registered Trademark

temperature rise to less than $5^{\rm O}$ F above room ambient ($75^{\rm O}$ F) and allow a heat loss of 16 btu/sq. ft. per hour to the ambient area with a $200^{\rm O}$ F temperature differential. Also, high efficiency insulation is required to maintain adequate temperature control of the Assembly/Sterilizer main chamber and ducting work.

Main chamber heat loss = 34,500 sq. ft. x 16 btu/sq. ft. = 552,000 btu/hr

Fan housing heat loss = $10 \times 1144 \text{ sq.ft.} \times 16 \text{ btu/sq.ft hr.} = 183,000 \text{ btu/hr}$

Supply and return duct losses approximately equal fan housing losses 183,000 btu/hr.

Lf pyro chamber and vestibule at heat at same time then:

Vestibule loss = 3744 sq.ft. x 16 btu/sq.ft. hr. = 60,000 btu/hr.

Pyro chamber = 720 sq.ft. x 16 btu/sq. ft hr. = 12,000 btu/hr

Total maximum heat loss = $(552+183+183+60+12) \times 10^3 = 990,000$ btu/hr. This is the heat loss into the building from the above listed sources and must be allowed for when designing the air conditioning systems for the surrounding areas. Note: It is also necessary to maintain room ambient temperatures above the chamber and in the equipment room below the chamber in the interest of maintaining a constant condition of heat flow from all surfaces of the chamber.

The total heating requirement is the sum of the external heat loss and the heat needed to raise the temperature of the gas in the system and the equivalent steel mass of the chamber frame at the required rate of 50° F per hour, less the fan horse power input.

Structural steel

350 Tons

Insulation, skin, equipment, housings, etc. 175 Tons

Equivalent steel

525 Tons

Heating for steel 525 tons x 2000 #/ton x .109 btu/F $\# \times 50^{\circ}\text{F}/\text{hr}$ = 5,525,000 btu/hr

Heating for the circulation air 432,000 cu.ft. x .018 btu/ft 3 0 F = 390,000 btu/hr

Heat loss to surrounding area = 990,000 btu/hr

Total heat requirement = 6,905,000

Fan input 11 x 100 hp x 1KW/HP x 3415 btu/kwh = 3,756,000 btu/hr

Net total heat required = 3,149,000 btu/hr.

The cooling capacity required for Assembly/Sterilizer main chamber temperature control at a sterilization temperature of 275° F is:

Fan heat input = $10 \times 100 \times 1$ KW/HP x 3415 = 3,415,000 btu/hr Heat loss through walls (approx) = $\frac{-900,000}{2,515,000}$ btu/hr

This cooling capacity would have to be provided by the heat exchangers in the back loop. With 10 ducting modules, the heat loss is approximately 250,000 btu/hr per module.

The cooling requirement during cool-down, at a rate of 50° F per hour, is the sum of the heat rejection from the equivalent steel mass and the heat rejection from the air and fans, less the heat loss from the room.

Fan drive heat	3,756,000 btu/hr
Heat from stee1	5,525,000
Heat from air	390,000 9,671,000
Heat loss from room	<u>- 990,000</u>
Cool-down requirement	8,681,000 btu/hr*

To maintain the 50°F per hour cooling rate down to ambient temperature the cooling load is 9,671,000 btu per hour because the heat loss from the walls becomes negligible as wall temperature approaches ambient.

It has been assumed that during the heat-up and cool-down cycles there was no heat-producing equipment, such as lights or power supplies, in operation in the Assembly/Sterilizer room. If such equipment is in operation during either cycle, its heat would add to the cooling requirement or lessen the heating requirement by its heat-producing rate. During the time the room is occupied as a sterilized assembly room, the cooling load will be the sum of internal loads only, as there will be no temperature difference between the Assembly/Sterilizer room and its enclosure. The load under this condition would be:

Lighting (72' x 100' + 24' x 24') x 8 watts/sq.ft. x 3.415 btu/wh = 214,000 btu/hr

Fan drives = 11 x 100 HP x 1KW/HP x 3415 btu/kwh 3,756,000

Constant operational and cooling load = 3,970,000 btu/hr

One more condition must be evaluated. The major portion of the cool-down load can be handled by the use of evaporative cooling (cooling towers). However, as the room design condition (75°) is

^{* (}This is in addition to the air conditioning requirement of the building enclosing the sterilizer complex)

approached, a change over to mechanical cooling must be made. The final 20° of cooling to ambient will not have the benefit of any significant heat loss from the room but will have all other loads except lights. For conversatism, the light load is included as part of the cooling requirement, as the operating personnel will in all probability have the lights on during the latter phase of the cool-down cycle.

Heat from drive, steel and air 9,671,000 btu/hr

Light load 214,000

Maximum mechanical cooling load 9,885,000 btu/hr

If the cool-down rate were reduced to 25° per hour, the heat rejection from the steel and air mass would be halved, reducing the mechanical cooling requirement for the last 20° of cool-down and keeping the lights off, then:

Fan drive 3,756,000

Steel heat rejection 2,762,000

Air heat rejection 200,000

Economy cooling load 6,718,000 btu/hr.

D. STRUCTURES

Although a detailed structural analysis of the Assembly/Sterilizer or the building is outside of the scope of this study there are several structural aspects of the design have been investigated.

1) Building Structure

The tentative building structure recommendation is the use of steel girder construction with a non-structural outside skin. Skin panels would probably be prestressed concrete or integral skin/insulation panels fabricated of aluminum.

The pyrotechnic area on the main floor would require reinforced concrete walls, ceiling, and floor, except for one outside wall which would be a lightweight loosely attached panel.

Selection of a foundation type will require further study based on exact site location information and a site survey. However, for siting at AFETR the foundation will probably consist of a floated reinforced slab, with minimum excavation using pilings for anchors.

2) Assembly/Sterilizer Structure

The basic material for the Assembly/Sterilizer main chamber inside skin will be stainless steel or a suitably clad mated panel. The skin will be suspended from a structural steel framework. Outside of the skin will be insulation and a light weight outer skin. The insulation that appears to be most suitable is rigid glass foam brick (approximately 9 lb/ft³ with a compressive strength of 100 psi).

A major structural problem is the expansion of the Assembly/Sterilizer main chamber at elevated temperatures. Structural steel has coefficient of linear thermal expansion of $7.22 \times 10^{-6}/^{0}$ F. With a chamber length of 96 ft. and a heat rise of $+70^{\circ}$ to 300° F, this is an overall growth in length of 1.91 inches. The suggested solution to this problem is to mount the Assembly/Sterilizer inner skin rigidly to a framework which is heated with the chamber walls and then to "float" the entire framework on the building foundation. An architectural structures consultant was retained by the General Electric company to perform a preliminary structural design for the Assembly/Sterilizer. The following discussion presents the results of this design.

(a) Structural Assumptions

- Internal static design pressure in the main chamber, vestibule and pyro oven is to be 12" H₂O or three times maximum operating pressure of 4" H₂O. Effectively this amounts to 60 psf and the main frame is designed to carry this pressure without exceeding safe working stresses.
- . Floor supporting the assembled flight vehicles are designed for a uniform loading of 250 lb. per sq. ft. and point loads of 5000 lbs. These figures allow for vehicle, bio-loading and supporting dollies or fixtures.

- . Heated skin is assumed to serve no structural function except to contain and transmit internal pressure loadings
- . Suitable gasketing material, such as a form of silicone rubber, exists and may be used in planning door and window systems.
- Any one of several food insulating materials may be used to contain the process heat; or perhaps several, in appropriate applications.
- . There must exist, or found, a good, hard, structurally strong thermal insulating material for use under base-plates of columns (300 psi), and as guides and fillers in door operating designs.
- . Blast conditions assumed in this concept:

Pyro-chamber

2000-3000 psf max with relief provided to let go at 10% of this pressure.

Main Chamber and Vestibule

150 psf max. with relief provided at 60 psf, the safe design capacity of the enclosure. Under maximum assumed pressure rise, without relief, the chamber should deform plastically to some extent, but without probability of general failure. These ad hoc assumptions are stated to permit some progress in development of a structural concept, but are subject to a careful review as further information becomes available.

(b) Structure Concept

The Assembly/Sterilizer will be constructed of structural steel fabricated on site with built-up panel sections welded in place for walls, ceilings, and floors. The basic structure will be essentially a free floating right parallelpiped composed of I beams. The basic structure is shown in figures E-25, E-26, and E-27. Figure E-25 shows a typical cross section through the main chamber as viewed from the pyrotechnic oven end; figure E-26 shows the roof framing; and figure E-27 shows the floor framing.

Figures E-28 , E-29 , and E-30, show the support scheme for the Assembly/Sterilizer. This scheme permits expansion of the system about the center of the bottom side of the lower plenum structure of the main chamber (Point "O" on figure E-28). The points "A", "B", "E", and "M" represent load bearing points for the system in plane with "O". The points "C" and "D" represent the centers of the interface openings between the main chamber and the vestibule and between the main chamber and pyro oven respectively and are not in the plane with "O".

The weight of the main chamber and its contents is borne on bearing points "A" and 'M". Points "M" are supported by 10WF33 I beam columns rigidly attached to the chamber frame at the top, and to the foundation at the bottom. During thermal expansion, these columns deflect in a compound bending mode along a line described by the origin "O" at the same location regardless of temperature. The points "A" are radially guided slide plates or roller nests on rigid 4 foot square concrete piers. The direction of motion of the bearings is along the lines OA.

Tha amount of deflection at any load bearing point at maximum system temperature is approximately:

y \sim .02 (length in feet from "0" to the bearing point) inches

The vestibule is framed in a manner similar to that used for the main chamber and is not detailed in the attached diagrams. The vestibule is supported at the outboard end on inclined sided plates parallel to the lines \overline{BC} stacked on plates parallel to the lines \overline{OC} . The plates parallel to \overline{OC} maintain proper positioning of the vestibule by accommodating main chamber expansion; and the plates parallel to \overline{BC} maintain positioning by accommodating vestibule expansion. At the in-board end, the vestibule is supported by its interface with the main chamber. The outboard support is shown in figure E-29 and the inboard support is shown in figures E-28 and E-31 with interface also shown in the latter figure.

The pyro oven is constructed of a re-inforced concrete shell lined with an insulated stainless steel jacket. (Figure E-30). The insulation minimizes the heat transfer to the shell, and thereby its thermal expansion. Thus the only expansion that must be accounted for in the mounting of the oven is that of the main chamber. This is achieved by inclined slide plates, at points "E", which are parallel to the line $\overline{\text{OD}}$. The mounting of the oven is shown in figures E-28 and E-30 and the interface with the main chamber is shown in figure E-32.

The mass of structural steel estimated for the structure described herein 350 tons.

3) Explosion Safety

The Assembly/Sterilizer facility must be considered, and designed, as an Explosive Safe Area (ESA). The rocket motors and other pyrotechnics used in the flight vehicle impose a substantial potential hazard to personnel and equipment. The facility and operating plans must be designed to minimize this hazard.

The philosophy for the design is blast channeling, rather than blast containment, in the event of an explosion. The pyrotechnic area and pyrotechnic oven in the selected building plan both have blow-out walls on the rear of the building. Building siting should

provide clear space for a substantial distance to the rear of the building to prevent injury to personnel, or damage to equipment, outside the building in the event of a blast.

The main chamber and vestibule have blast relief provisions in the form of blow out patches or panels in the upper plenum roofs. For the pyrotechnic oven this same scheme can be used in lieu of a blowout wall section.

Explosion relief can be considered in terms of panels on building outer walls, on roof or in terms of channels from panels inside the building ducting the explosive energy to the outside. The advantage of outside blow-out walls or panels over blast channels is that a blow-out wall directs the pressure wave into an untuned infinite baffle while the blast channel is inherently tuned to some resonant frequency. If blast channels are to be used, considerable information must be available about the frequency spectrum of explosions of the pyrotechnics to be processed in the facility so that blast channel design does not permit channel resonances to coincide with frequency peaks of the blast spectra. If this were to occur, disasterous pressure wave reinforcements could result.

A preliminary analysis has been made of pressure relief techniques. This analysis suggests that explosion relief for the main chamber and vestibule will probably have to be achieved by multiple rupture diaphrams. Displacement of panels may be satisfactory for the pyro oven. The analysis is contained in attachment 2 hereto.

It should be noted that explosion safety should also be considered when making a final selection between vertical and horizontal positioning of flight vehicle sections containing pyrotechnic devices. The vehicle sections should be positioned such that the line of thrust of an inadvertently ignited device is directed towards the least populated parts of the building. This consideration also argues in favor of reserving the main floor of an Assembly/Sterilizer building for those activities which must be at that level.

2

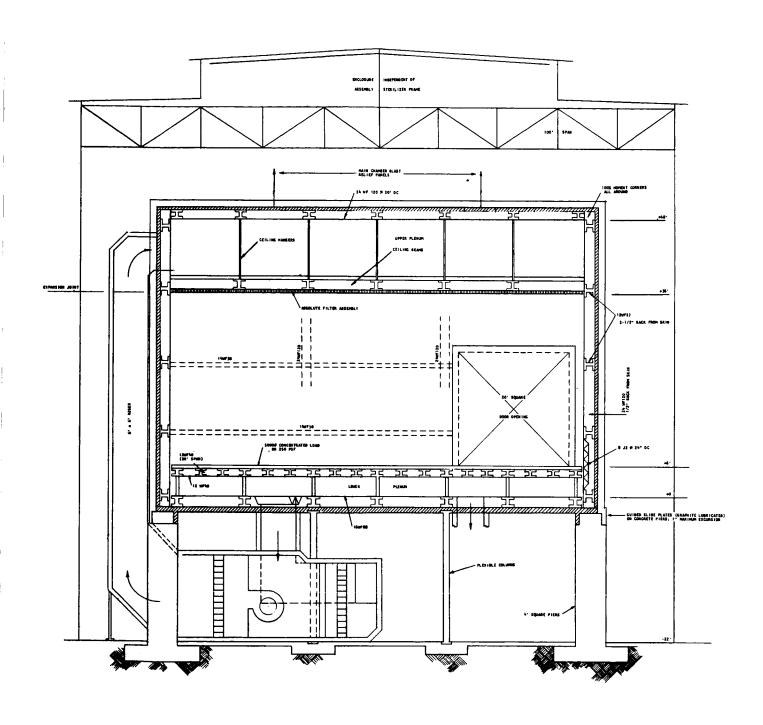


FIGURE .E-25 MAIN CHAMBER FRAMING END VIEW

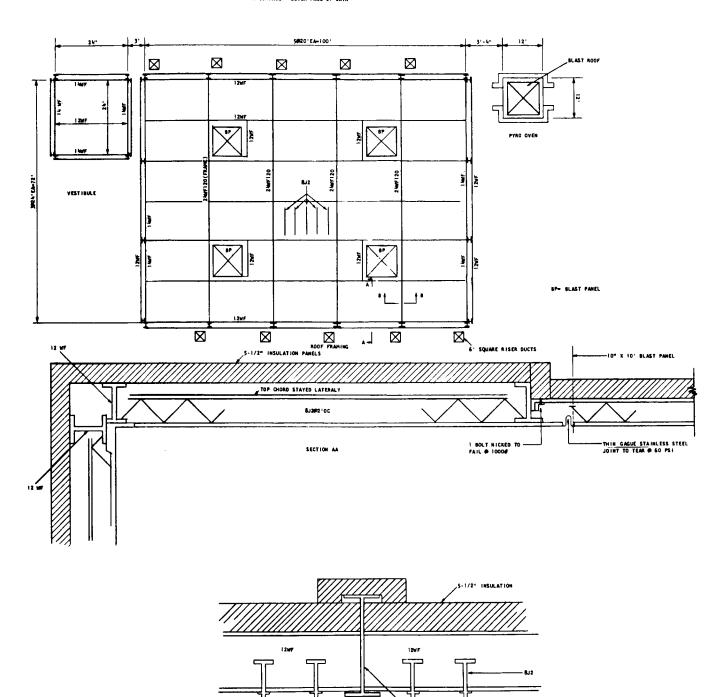


FIGURE E-26 = FACILITY ROOF FRAMING

SECTION BB

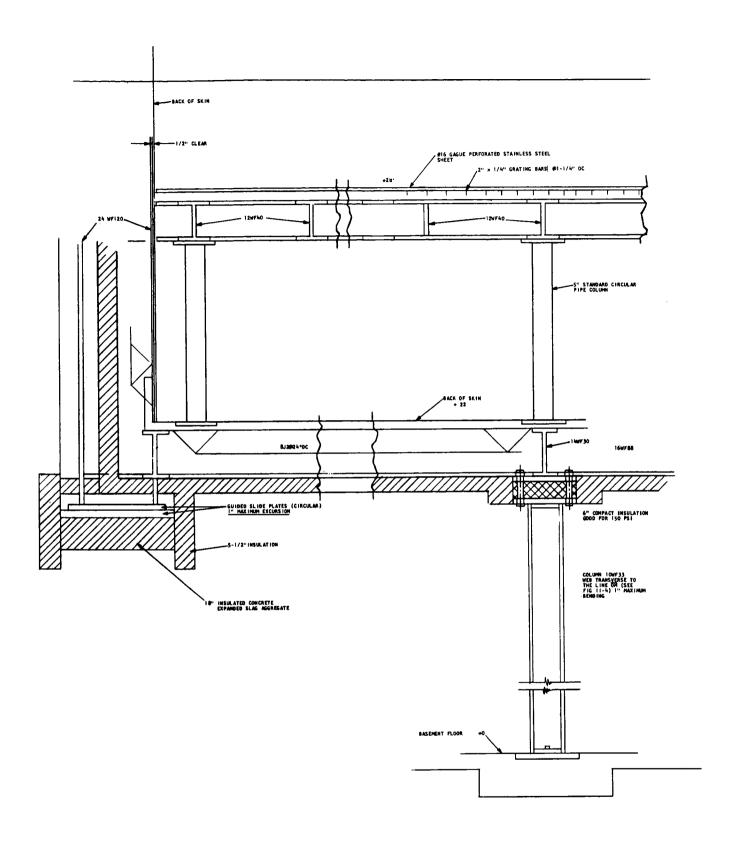
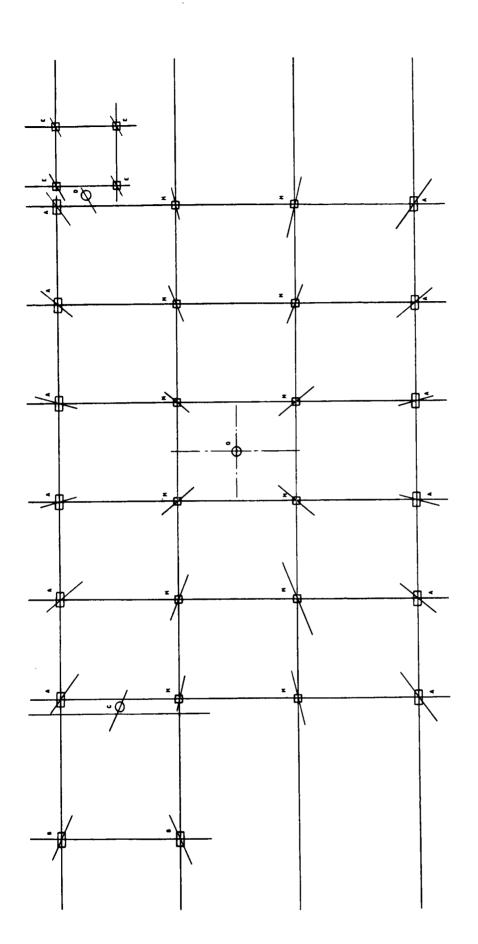
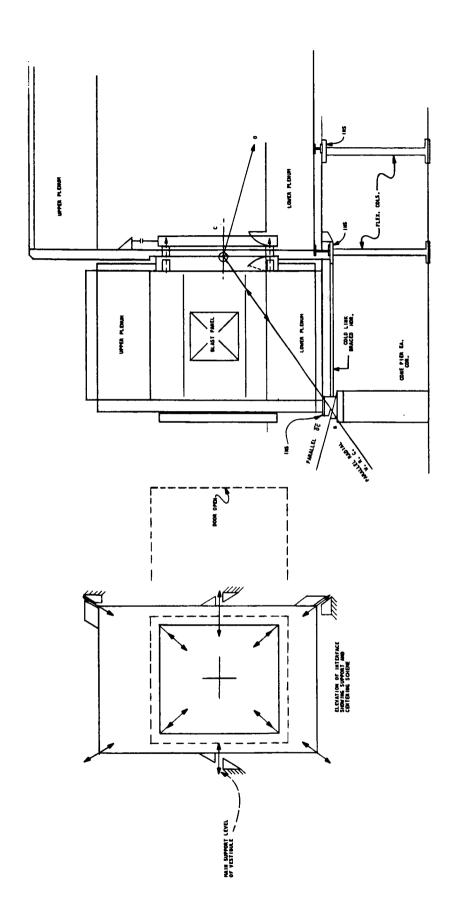


FIGURE E-27-MAIN CHAMBER FLOOR FRAMING AND SUPPORT



- HISULATED, RADIALLY GUIDED SLIDE PLATES ON ROLLER MESTS ON ÁIGID CONCRETE PIERS INSCLÁTED FIERD BERNINGS ON PLOTIBLE STEEL COLUMNS

FIGURE E-28 - SYSTEM LOAD BEARING SUPPORT PLAN



OUTDOOR SEPOND TROY IS INC.

VESTIBLE COLD.

ANI CHAREE HOT

I VESTIBLE FOR

HAIR CHAREE HOT

II DOTH CHAREES HOT

I'VESTIBLE FOR

I'VESTIBLE

FIGURE E-29 - VESTIBULE SUPPORT AND ALIGNMENT SCHEME

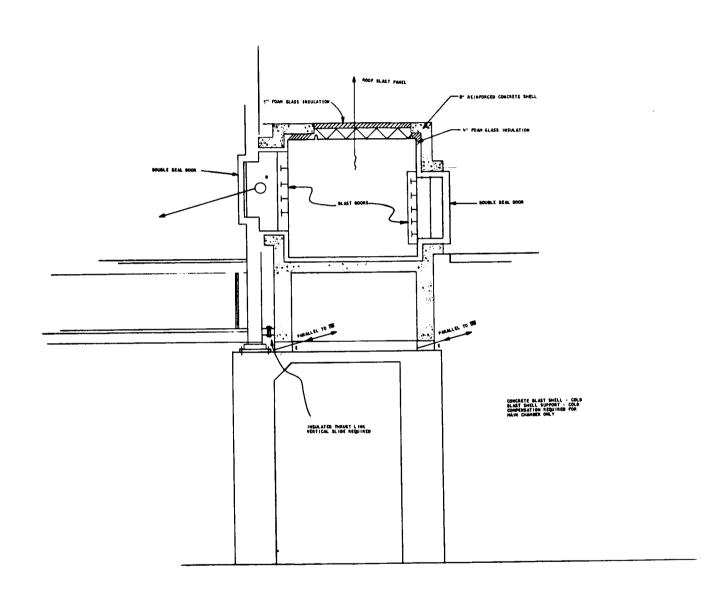


FIGURE E-30-PYRO OVEN SUPPORT AND ALIGNMENT SCHEME

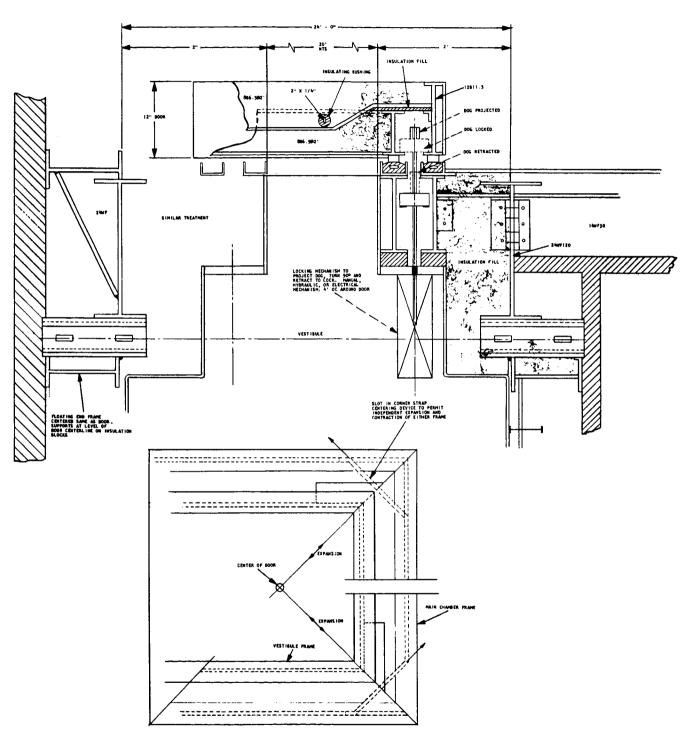


FIGURE E-31-VESTIBULE/MAIN CHAMBER INTERFACE

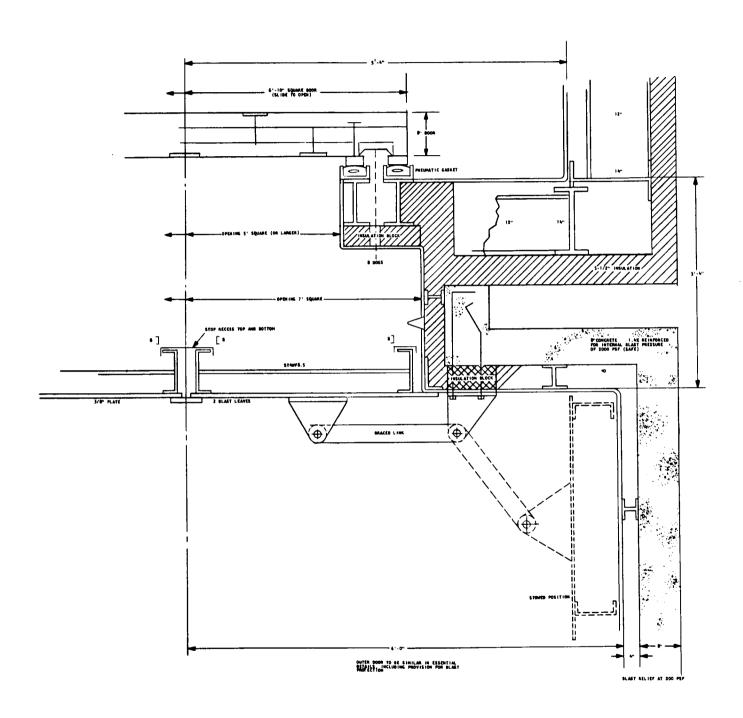


FIGURE E-32-PYRO OVEN/MAIN CHAMBER INTERFACE

COST ESTIMATES

The evaluation and conclusions of Section E on building layouts lead towards building plan B as the one best satisfying the facility requirements. Thus the following estimates are based on this plan.

A facility will be required at the launch site for the Assembly, sterilization, checkout, and repair of large interplanetary lander vehicle.

To establish a suitable context for evaluation of the cost estimates presented below are based on definition of the cost differential between design and construction of this facility and the design and construction of a facility to perform the required tasks using mere conventional techniques (i.e. terminal sterilization of a lander sealed in a biobarrier).

To optimize the efforts towards taking full advantage of any launch window, the facility for processing of sterile landers should have capability for simultaneous processing of two landers. Independent studies* have shown that the controlled environment floor space required for each lander is on the order of 7000 to 6500 square feet. In the Assembly/ Sterilizer facility approximately 7000 square feet is allocated to the clean room and an equal amount of floor space is allocated to the Assembly/ Sterilizer main chamber. In a more conventional facility, approximately 14,000 feet would be allocated to two clean rooms, which would preferrably be separate. Further, since the clean room and the A/S main chamber heightsaare the same, the total building height and cubage would be equivalent for both the A/S facility and the conventional facility.

A chamber of the approximate size of the vestibule would be required in a conventional facility to permit decontamination and sterilization of the landers.

For any Assembly/Sterilizer building layout the following changes would be made in the floor plan to convert it to a class 100 clean assembly building with two 7000 square foot clean rooms.

- Replace A/S main chamber by "conventional" class 100 vertical laminar flow clean room.
- Locate vestibule to service both clean rooms without disrupting material flow to either.
- . Locate pyro area to service both clean rooms.

^{* &}quot;Voyager Capsule Pre-Proposal Facility Study" November 1965. Prepared for GE Re-entry Systems Department by Jackson and Moreland, Boston, Mass. (A division of United Engineers and Constructors, Inc.)

- . Delete pyro oven
- Delete approximately 75% of BISS Service area convert remaining 25% to clean room preparation for second room.
- Delete approximately 75% of A/S control and observation area convert remaining 25% to clean room observation.
- . Provide redundant AGE and RF for both clean rooms.
- . Delete pass-through area.
- Locate shipping and receiving and cleaning areas to service both clean rooms.

While it is recognized that these changes would require a complete reevaluation of building layout, it felt that with presently available information the cost comparison between the conventional facility and A/S facility can best be seen in light of estimation of the differences between the A/S facility of plan B and the cost of the same facility reflecting the above listed changes except for the relocation of areas.

Although results of studies on conventional facilities are available, these studies were performed by different groups than the group doing the A/S study and were performed under different ground rules. Thus, a direct comparison between the results of the past studies and the present study does not provide a good basis for evaluation of the differential costs associated with the A/S facility.

Therefore in approaching the problem of roughly estimating the cost of a full scale facility, primary dependence has been placed upon the cost of and experience with the Assembly/Sterilizer analogue. In projecting the cost from a single fixed point, the following assumptions have been made:

- 1) As the scale of the Assembly/Sterilizer increases, the cost will vary as a function of the total surface areas independently for the two major segments; i.e. a) the structure skin, ducting and thermal subsystems and b) the monitoring and control subsystems.
- 2) The cost for the structure skin, ducting and thermal subsystems will be directly proportional on a one to one basis per unit total surface area.
- 3) The unit cost for the monitoring and control subsystems is inversely proportionate to the total surface area.

As a basis for calculating the full scale facility cost, the following data are used.

1) Cost of Assembly/Sterilizer Analogue

Structure Skin, Ducting and thermal \$300/sq. ft. Monitoring and Control \$600/sq. ft.

2) Total Surface Area

Analog 100 sq. ft. Full Scale 40,000 sq. ft.

Based upon the comparison of control complexity to system size, it has been concluded that the unit cost for the Monitoring and Control Subsystems will decrease by a factor of four (4) between the 100 sq. ft. analogue and the 40,000 sq. ft. Full Scale facility.

Considering the above assumptions and data graphically represented in Figure E-33, the estimate for the Full Scale Facility then becomes:

Structure Skin Ducting and Thermal

40,000 sq. ft. @ \$300/sq. ft. \$12,000,000

Monitoring and Control

40.000 sq. ft. @ \$150/sq. ft. 6,000,000

BISS Units

10 @ \$100,000/unit 1,000,000

BISS Support Areas 250,000

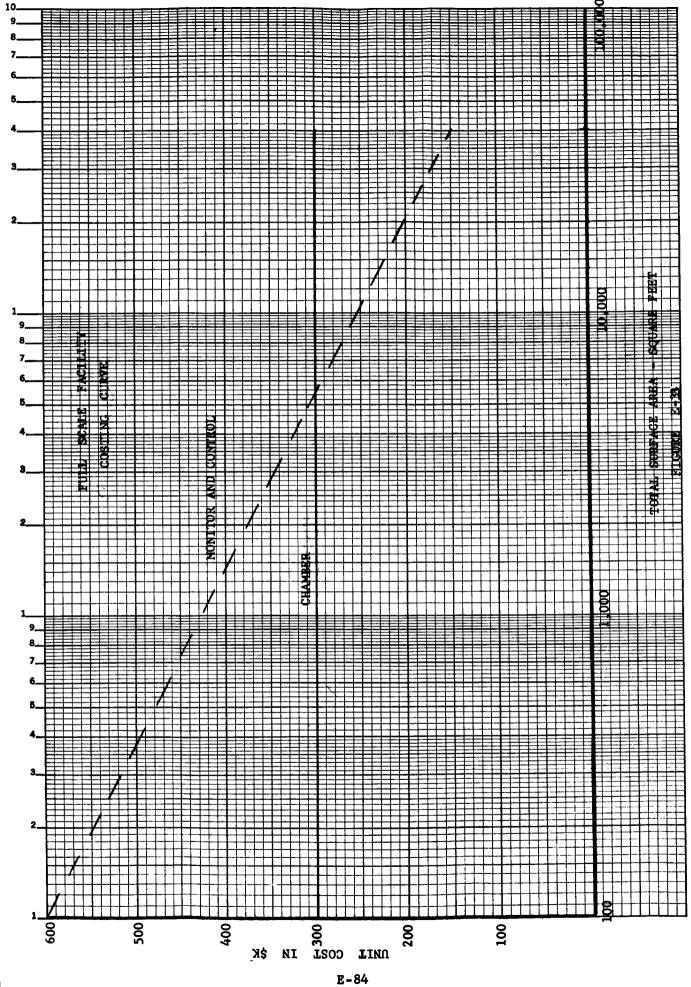
Omissions and Contingencies @ 20% 3,850,000

TOTAL \$23,100,000

The above estimate considers the Assembly/Sterilizer as a delta to the estimated cost of a decontamination, final assembly, terminal sterilization facility. Based upon the GE funded Jackson and Moreland Report* and the report prepared by Richard Jenney** under contract to the General Electric Company under this contract it is estimated that the Auxillary Structures and facilities to support the Assembly/Sterilizer System will approximate the cost of and replace a Terminal Sterilization facility.

^{*} Voyager Capsule Pre-Proposal Facility Study, November 1965.

^{**} Structural Conceptual Design--Assembly/Sterilizer Full Scale Facility Study, May 1966



ATTACHMENT 1 TO

APPENDIX E

ASSEMBLY/STERILIZER MATERIAL FLOW

The processing of the equipment in the Assembly/Sterilizer is covered by three basic material flows: the "normal Flow" in which the vehicle is processed with no vehicle system's malfunctions' the "Repair Flow" in which the normal flow is disrupted by detection of a vehicle malfunction; and the "Recycle Repair Flow" in which a vehicle must be recycled for repair due to a malfunction detected after the vehicle is removed from the Assembly/Sterilizer (e.g. an on-pad malfunction).

(1) Normal Flow

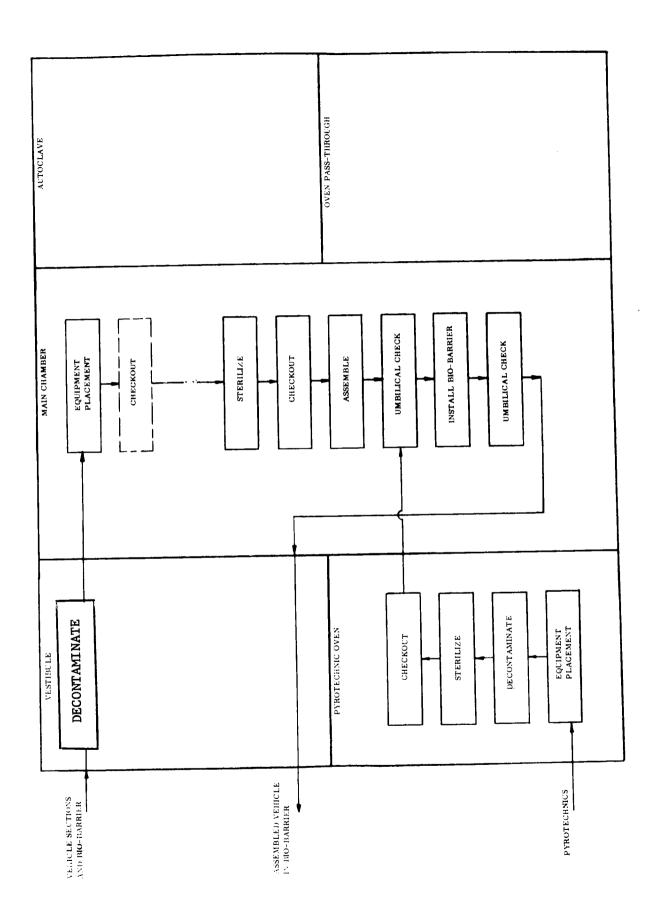
The "Normal Flow" is shown in Figure 1-1. The vehicle sections are inspected and checked out in a class 100 clean room outside the Assembly/ Sterilizer. Assuming satisfactory results, the vehicle sections are transferred to the vestibule and the vestibule is sealed and leak checked. Leak checking can be accomplished by adding a trace gas, such as, helium, to the chamber gas and checking seals with a mass spectrometer of similar detector. Then an ETO/FREON decontamination treatment is initiated in the vestibule. During this treatment, the main chamber can be subjected to a dry heat load reduction treatment if it was not left in a low load condition at the end of the last system cycle. Also heat load reduction of vehicle equipment or sections can be performed in the main chamber during this period.

Following the ETO/FREON treatment in the vestibule, the vehicle sections are transferred to the main chamber and laid out in such a manner as to maximize the exposure of all internal and external surfaces to the chamber atmosphere. If desired, the vehicle sections can again be checked out before proceeding. The main chamber is then closed up and leak checked, using techniques similar to those used for the vestibule. After the leak check, the dry heat sterilization cycle is performed.

After post-sterilization cool-down, workers enter the BISS suits and connect the vehicle sections assemblies, or components to electrical test cables which are attached to external test consoles through connectors on the chamber wall.

While these operations are being performed identical operations are being performed on the pyrotechnics in the pyrotechnic oven. The primary difference being that the test cables are connected to the pyrotechnics from the time of placement in the oven till transfer to the main chamber since there are no provisions for suited operators to enter the sterile pyrotechnic oven except through the doors from the main chamber.

When the checkout and any necessary adjustments have been completed successfully, the vehicle is assembled and the pyrotechnics are transferred to the main chamber and installed in the vehicle. Upon completion of vehicle assembly, the condition of the vehicle system is confirmed through the pre-launch and flight-umbilical connectors. The bio-barrier is then installed, sealed and checked, and umbilical check is repeated.



The bio-barrier-encased, fully operable vehicle is then removed through the vestibule and is ready for short term storage or mating with the spacecraft.

In removing the vehicle from the Assembly/Sterilizer, the main chamber to vestibule door can be sealed before the vestibule outer door is opened, thus leaving main chamber in a decontaminated condition. (If the vestibule were sterilized during the main chamber operations, the main chamber would be left sterile upon vehicle removal).

(2) Repair Flow

The "Repair Flow" is shown in Figure 1-2. This flow proceeds in the same manner as the "Normal Flow" until one of the checkouts reveals a system defect. For the purposed of illustration it is assumed that this defect is detected in the post-sterilization checkout.

After malfunction detection in the checkout, the fault will be isolated to the smallest replaceable component. The defective component will then be removed. A replacement unit will be introduced to the main chamber through the vestibule, autocalve, or oven pass-through. The selection of the means of introduction will depend upon the size of the replacement unit and its tolerance to steam.

Any large unit would be introduced through the vestibule, being decontaminated with ETO/FREON and sterilized with dry heat in the vestibule. The unit would have been checked-out prior to placement in the vestibule and the checkout would be repeated immediately upon introduction to the main chamber.

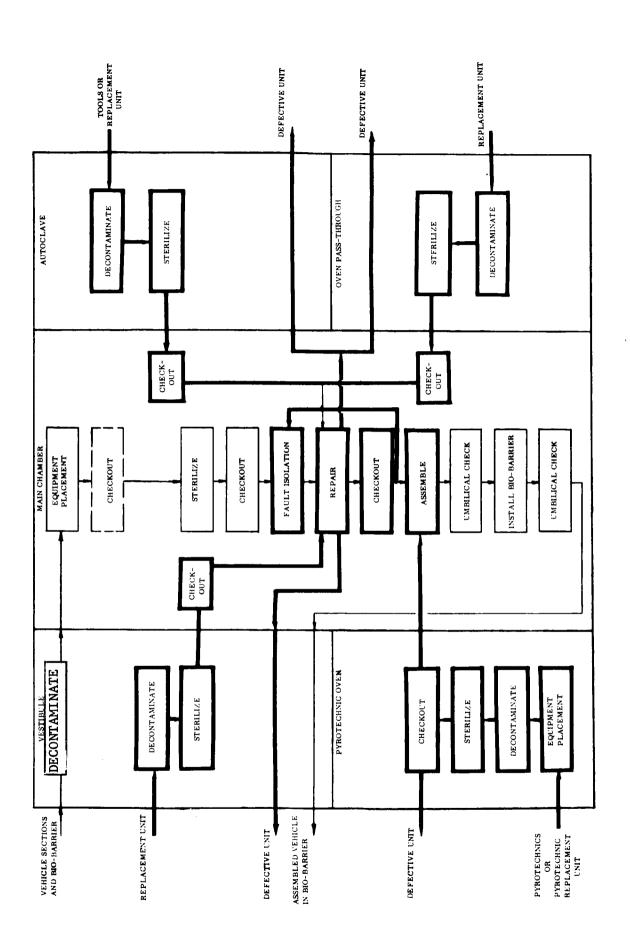
Tools or small units which can be sterilized by steam would be introduced through the autoclaves. This provides a much shorter delay in introduction because of the shorter kill times for wet heat than for dry heat. Small units or tools not tolerant of steam can be introduced through the oven pass-throughs.

After the replacement unit has been introduced to the main chamber and checkedout, the repair of the defect is performed. Repair in the main chamber will consist only of replacing defective units -- soldering, welding, riveting, sawing, and similar "dirty" operations will not be permitted.

After repair, the vehicle sections are checked-out. If the repair has not been effective, the sections are again submitted to fault isolation and further repairs are made by sterile introduction of additional replacement units. If the repair has been effective, the vehicle porcessing again proceeds as in the "Normal Flow".

From the standpoint of hardware flow in the facility, sterile insertion of capsule equipment or experiments can be viewed the same as repair except that there would be no defective unit to remove from the main chamber.

Replacement of defective pyrotechnics will be handled differently than for non-pyrotechnic units. The defect in a pyrotechnic device which failed due to sterilization, for example, could be detected while the device was still in the pyrotechnic oven. However, normally there would be several devices in the oven simulatneously. Thus, the good devices would be transferred to the main chamber in the normal manner after sterilization and checkout, while the defective unit would be left in the oven for removal to the outside after the oven doors to the main chamber had been closed. A replacement pyrotechnic



device would then be placed in the oven, decontaminated, sterilized, checked-out, and transferred to the main chamber.

(3) Recycle Repair

The "Recycle Repair Flow", shown in Figure 1-3, differs from the "Repair Flow" just described in the steps leading up to fault isolation.

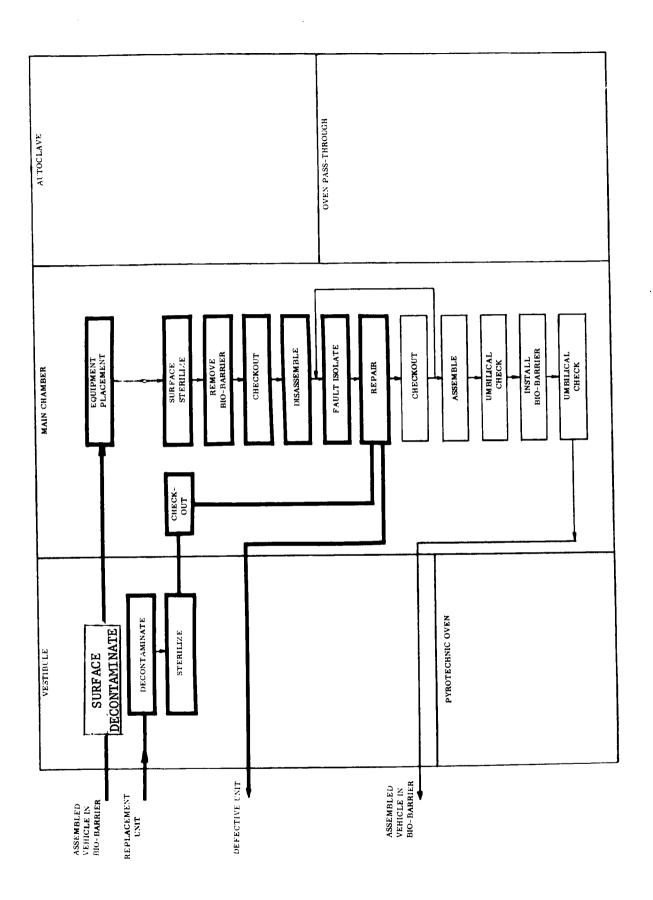
A defect in the vehicle, encased in its bio-barrier, is detected at some point outside of the Assembly/Sterilizer, such as on the launch pad. The vehicle is then returned to the Assembly/Sterilizer for fault isolation and repair.

The sterile vehicle in its bio-barrier is introduced into the main chamber. It is necessary only to decontaminate and sterilize the main chamber and the outer surface of the bio-barrier because the vehicle is still sterile. Thus the thermal exposure that the inner parts of the vehicle experience is much less than that which they would experience if it were necessary to sterilize the full vehicle.

To fully realize this advantage, it would be necessary for the bio-barrier to possess good thermal insulation properties. In contrast, if a vehicle were to be processed in a facility whose concept was based on sterilization after assembly, it would probably be desirable to have the bio-barrier provide good thermal conductivity.

After sterilization, the bio-barrier is removed, the vehicle is checked-out, disassembled, fault isolated, and repaired. After repair, the flow is the same as the "Normal Flow".

If the main chamber had been left in a sterile condition after the last equipment was removed prior to initiation of "Recycle Repair", the surface sterilization of the bio-barrier could be performed in the vestibule with a considerable saving in power.



APPENDIX E ATTACHMENT 2

ASSEMBLY/STERILIZER BLOW-OUT ANALYSIS SUMMARY

1.0 Introduction

The pressure in a closed vessel due to ignition of a pyrotechnic device may be expected to have a form as shown in Figure

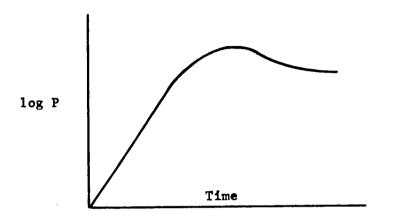


Fig. 2-1 Pressure buildup with no relief.

It is desired to provide pressure reliefs to prevent damage due to this build-up of pressure. The desired result would be as shown in Figure

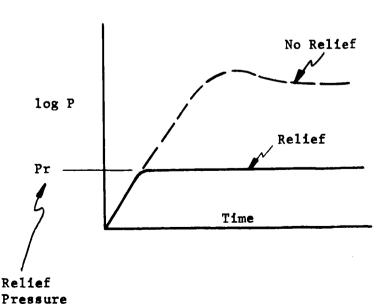


Fig. 2-2 Pressure build-up with relief (optimum).

In actual practice the curve of Figure 2-2 would look more like that of Figure .

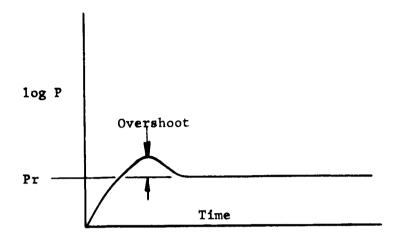


Fig. 2-3. Pressure build-up with relief ("actual").

The overshoot is due to the fact that the relief will not be instantaneous.

Two basic schemes have been examined as possible means to relieve the pressure. They are (1) displacement of a patch or wall section and (2) rupture of a frangible disc.

2.0 Analysis

A. Displacement Patch

Two means of implementing the displacement patch are shown in Figure 2-4. Equations of motion for each implementation are given below.

Pressure

Pressure

A - Lateral Translation

Pressure

Pressure

B - Rotational Blow-out

Lateral Translation

Blow-out

$$\frac{d^2x}{dt^2} = \frac{F}{M} = \frac{PA}{M}$$

$$\frac{dx}{dt} = \frac{PA}{M} t$$

$$x = \frac{PAt^2}{2M}$$

$$t = \sqrt{\frac{2MX}{PA}}$$

F = Force, Pounds

M = Patch Mass, Slugs

 $a = Acceleration, Ft/Sec^2$

P = Pressure, PSF

 $A = Patch Area, Ft^2$

t = Time, Seconds

X = Displacement, feet

Assume a step pressure function of amplitude P as the driving force.

If the patch has an equivalent thickness of 1 inches and is assumed made of steel plate:

M
$$\approx \frac{40 \text{ A}}{32.2}$$
 k slugs where 40 = density of steel in pounds per square foot per inch of thickness thus t $\approx \sqrt{\frac{2.5 \text{ kg}}{P}}$

As an example:

For
$$l = 1$$
 in.
 $X = 1$ ft.
 $P = 250$ PSF = 1.74 psi = 48 in. H_2O
 $t = \sqrt{\frac{2.5 \times 1 \times 1}{250}} = .1$ sec.

Rotational Blow-out

For this analysis the patch is considered as a uniform plate hinged at the center of the bottom edge and the thickness is considered negligible relative to the width and length.

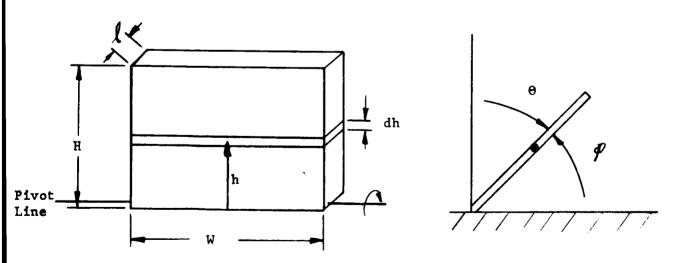
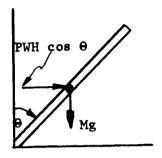


Fig. 2-5-Rotational Definitions

$$T = I \propto = I0$$

where I = Moment of Inertia

T = Torgue Θ = Angular Acceleration



 $I = \frac{MH^2}{3}$

Fig. 2-6 Force Diagram

$$T = \frac{H}{2} PWHcos^2\Theta + \frac{H}{2} mg sin \Theta$$

P = Pressure

W = Width of Patch

H = Height of Patch

M = Mass of Patch

G = Gravitational Constant

$$\ddot{\theta} = \frac{T}{T} = \frac{3PW}{2M} \cos^2\theta + \frac{3g}{2H} \sin \theta$$

The first derivative is found by:

$$\frac{d \cdot (\theta^{2})}{d\theta} = 2 \frac{d^{2}\theta}{dt^{2}}$$

$$\dot{\theta}^{2} = \int_{0}^{\theta} \frac{3PW}{2M} \cos^{2}\theta d\theta + \int_{0}^{\theta} \frac{3g}{2H} \sin \theta d\theta$$

$$= \frac{3PW}{2M} \left[\frac{1}{2} \theta + \frac{1}{4} \sin 2\theta \right]_{0}^{\theta} + \frac{3g}{2H} \left[-\cos \theta \right]_{0}^{\theta}$$

$$\frac{d\theta}{dt} = \dot{\theta} = \left[\frac{3PW}{2M} \left(\frac{1}{2} \Theta + \frac{1}{4} \sin 2\Theta \right) + \frac{3g}{2H} \left(1 - \cos \Theta \right) \right]^{\frac{1}{2}}$$

This equation does not submit to ready solution. However, without extensive further analysis, it can be said is that the time required to open the rotational patch will probably be on the same order of magnitude as the time to open the lateral translation patch if the pressure times patch area is of the same order of magnitude as the patch weight. If the pressure times patch area is much less than the patch weight, the rotational patch will open faster; and if the pressure times patch area is much greater than the patch weight, the translational patch will open faster.

In either case it appears that with realistic door masses, the door opening would be much slower than that required to the relieve pressure build-up due to explosion of a large pyrotechnic (such as a retro-rocket).

B. Frangible Disc.

A rupture diaphram would be a thin membrane disk of metal with cuts scored across its face on two orthogonal diameters. This disc would have to be heated electrically to minimize disc mass. Caution would have to be exercised to insure that system thermal expansion did not cause disc rupture.

Even a preliminary quantitative analysis of this relief scheme would be of great complexity. At this time, however, it can be said that rupture diaphrams of at least twelve inches in diameter are presently being made; and that the ratio of relief pressure to working pressure for such diaphrams is much lower than likely for a moveable patch system. Also a rupture diaphram would, by its nature, be much less massive than a practical displacement patch system and should, therefore, have a much faster reaction time.

3.0 Conclusions

The final design of any blow-out system will necessitate detailed definition by NASA of the explosive characteristics for all major pyrotechnics to be processed in the Assembly/Sterilizer.

The rupture patch appears to be the approach most meriting further study. However, for such a study to be meaningful, it would be necessary to have the date on the pyrotechnics and to conduct laboratory tests on diaphrams with simulated explosions.

All ducting leading from pressure reliefs to the outside must be designed to prevent quarter wave stubs at any dominant acoustic frequencies from the explosions.

For a small closed system, such as the pyrotechnic oven, the displacement patch may be suitable since higher pressures will be experienced and can be tolerated. In consequence, faster relief times will result.

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